The health and well-being of individuals before and after coronary artery bypass surgery

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Abstract

Introduction

Coronary artery bypass graft (CABG) surgery is an important intervention for individuals with established coronary heart disease (CHD). Although its place as one of a range of therapeutic options has been established, outcome assessment is based almost exclusively on biomedical measures such as mortality and morbidity. Much less is understood about benefits to general health and well-being, broader life circumstances and the expectations of those undergoing this procedure, particularly the manner in which these factors influence the favourability of the outcome. The objective of this thesis was to investigate these issues.

Objectives

- To assess the health status, in broad terms, of subjects before and after CABG surgery;
- To examine the association of pre-operative health status with changes in health status post-operatively;
- To document the expectations of benefit and the actual experience of undergoing CABG surgery from the patient perspective.

Subjects and Methods

The study was designed as a prospective descriptive study employing methodological triangulation. Subjects (n=215) were recruited from the waiting list for elective CABG surgery (as a single procedure) approximately one month prior to expected surgery date. Subjects were assessed prior to surgery in terms of (i) socio-demographic indices including social networks (ii) deprivation category (iii) CHD symptoms and risk factors (iv) eight dimensions of short form-36 (SF-36) health survey questionnaire (v) health locus of control and (vi) interviews to document impact of CHD to health, expectations of surgery and life after the operation. The same measures were used to re-assess subjects at 16 months after surgery.

Main outcome measures

Self-rated levels of angina and breathlessness symptoms (rating scales), SF-36 health survey questionnaire, presence of the main CHD risk factors and thematic analysis of structured interviews.

Results

- 55% of subjects were relieved of angina and 36% relieved of breathlessness symptoms at follow-up assessment. Of those with symptoms, the mean self-rated score was highly significantly reduced, (angina $p<0.001$, breathlessness, $p=0.02$).

- Older subjects were more likely to be relieved of angina and breathlessness symptoms ($p<0.001$). Past smoking, socio-economic deprivation category, alcohol intake, diabetes mellitus, health locus of control, plasma cholesterol or blood pressure level have no significant effect on whether or not a subject is totally relieved of angina or breathlessness symptoms following CABG surgery.

- Health status (SF-36 scores) following CABG surgery was statistically significantly improved ($p<0.001$) across all of the eight domains. A higher social network score was associated with improved health status.

- Lower levels of health (SF-36 scores) following surgery were largely influenced by the presence of angina and breathlessness symptoms, the presence of diabetes mellitus and to a lesser extent by current or past smoking, elevated plasma cholesterol levels, a high

socio-economic deprivation category, a higher number of uncorrected CHD risk factors, higher alcohol intake, and external health locus of control.

- Subjects with lower health levels (SF-36) prior to CABG surgery were less likely to be relieved of angina or breathlessness ($p<0.001$) and gain less improvement in health (SF-36) following CABG surgery.

- Health status (SF-36 scores) was lower than that of other CHD patient groups before surgery and lower than that of a large general population sample at 16 months after surgery.

- The majority of subjects had three and four uncorrected CHD risk factors at pre-operative and post-operative assessments.

- Subjects who attended cardiac rehabilitation had improved health status as measured by the SF-36 scale across all eight health domains. There was no difference related to attendance pattern in terms of the presence of uncorrected CHD risk factors ($p=0.25$) or presence/absence of CHD symptoms.

- Subjects' recall of level of these pre-operative angina and breathlessness symptom levels following CABG surgery were shown to be accurate and may therefore be a useful clinical outcome measure.

- Subject reports on health and well-being focused on issues of dependency and the threat of a sudden major cardiac event or death occurring without warning. Expectations of the benefit to health from CABG surgery were varied and uncertain and included the hope for freedom and independence, extended life expectancy and improved quality of life.

- The benefits of surgery were described in terms of 'removal of a death sentence' and the freedom to 'get on' and live a life as desired. The experience of CABG surgery was viewed as a very difficult process with 'lay support' being a valued and important source of help.

Conclusions

Following CABG surgery 55% of the subjects experienced relief of angina, 36% relief of breathlessness with a mixed picture of improvements in health status across the eight dimensions of the SF-36 scores. Subjects who experienced relief of symptoms and improved general health (SF-36) were generally older, reported less CHD symptoms prior to surgery, had higher scores for general health (SF-36), were non-diabetic and had richer social networks of support. A wider awareness of factors that are associated with favourable outcome may lead to better patient selection.

This cohort of patients was less healthy prior to surgery than corresponding groups of CHD patients from other published series. Expectations of the benefit to health from CABG surgery were varied and uncertain and suggest that patients require much more support, information and counselling of expectations prior to surgery. Many subjects had enormous expectations of the potential benefits of the procedure.

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Declaration

The work presented in this thesis was performed solely by the author, except where the assistance of others is acknowledged.

Dedication

To the memory of my mother.

'she who was the heart
and hinge of all our learnings and our loves'

Wordsworth, The Prelude, 1805.

Table of Contents

List of Tables

List of Figures

Glossary

BMI	Body mass index
CABG	Coronary artery bypass graft
CHD	Coronary heart disease
CR	Cardiac Rehabilitation
DBP	Diastolic blood pressure
DM	Diabetes mellitus
EF	Ejection fraction
GGHB	Greater Glasgow Health Board
HLOC	Health locus of control
ICD	International classification of diseases
LAD	Left anterior descending (coronary artery)
LV	Left ventricle
LIMA	Left internal mammary artery
MI	Myocardial infarction
MM Hg	Milli-metres of Mercury
MONICA	Monitoring of disease trends in cardiovascular disease (WHO Epidemiological study)
NYHA	New York Heart Association
PTCA	Percutaneous transluminal coronary angioplasty
ECG	Electrocardiogram
SV	Saphenous vein
SBP	Systolic blood pressure
SF-36	Short form-36 (health measurement questionnaire)

Chapter 1

1.1 General Introduction

The idea for this study originated from a small-scale audit project (Lindsay, Tait, Lorimer, Shepherd, Carter et al, 1995) to assess the prevalence of coronary heart disease (CHD) risk factors in patients undergoing coronary artery bypass graft (CABG) surgery that I undertook in 1992. This work revealed that many of the known CHD risk factors, both lifestyle and medical, were uncorrected in these patients, highlighting a potential area that might influence outcome of cardiac surgery. In light of these findings, this larger study was planned to examine in more detail, broad aspects of the health of patients before and after CABG surgery, including the patients' account of the experience.

CABG surgery has an extensive literature emanating from centres in the United States, Australia and European countries. The effectiveness of CABG surgery has been the focus of much of the literature with the main end-points described in terms of the biomedical outcomes of survival, reduction in further cardiac events and relief of symptoms. Clinical trials based on both observational and randomised controlled designs have been conducted in order to document the outcome benefits of this procedure. The general consensus of these trials support the efficacy of CABG surgery in terms of extension of survival and relief of symptoms. However, it has been acknowledged that the transferability of the results of these trials to a general population and to an individual patient can be problematic because of selective clinical criteria for entry to the trials, socio-demographic differences together with changing surgical and medical therapies.

Given the difficulties experienced by other researchers who have attempted to determine the outcome of CABG surgery in narrow biomedical terms, it is beyond the scope of a study of the size reported in this thesis, to demonstrate a causal relationship between outcome following CABG and pre-operative factors, or to investigate possible survival benefit since prognosis requires very long term follow-up. The literature reviewed has described health from a theoretical perspective and its measurement using quantitative questionnaire instruments and subjective accounts by

individuals. The concept of outcome measurement in general is examined and its application in the measurement and evaluation of health and quality of life discussed. Measures that have been developed and used in the study to assess health status from a multi-dimensional perspective have been reviewed. Psychosocial determinants of health have been considered from three main perspectives, that of socio-economic deprivation, social networks and health locus of control. The relationships of these factors to health in general and in the context of CHD and CABG surgery specifically are explored.

The aetiology and pathophysiology of CHD are described and their clinical consequences at an individual and population level are presented. The risk factor hypothesis is described and the evidence to support the main CHD risk factors summarised together with treatment targets that are currently available. The evolution of CABG surgery as a treatment modality in the management of CHD has been reviewed from a historical perspective describing the early attempts to revascularise the myocardium through to today's current approach using both internal mammary artery and saphenous veins as grafts. Indications for surgery and trends in rates of surgery both regionally, nationally and internationally have been reviewed together with the studies examining health outcome. Three major randomised controlled trials comparing surgical intervention with medical treatment have been conducted and the outcome of these studies has been reviewed and the conclusions in terms of guidelines for current practice are summarised. The impact of the major CHD risk factors on the development of atherosclerosis reviewed earlier in the literature, is revisited in terms of the influence on surgical outcome. In addition, the relative differences in fate of arterial and venous grafts are examined.

The secondary prevention of further coronary events in patients with established CHD including those patients who have undergone CABG surgery is provided through cardiac rehabilitation. The evidence to support the efficacy of cardiac rehabilitation is reviewed together with the main components of such programmes and the general outcome measures that have been used to evaluate these programmes. Studies that have examined expectations of surgery from the patients' perspective have been reviewed, together with work that has investigated from the patients'

perspective, the symptoms of living with coronary heart disease and the impact it has in day-to-day life. This background sets the scene for the work that has been undertaken within this study, placing the study in the context of other work that has been conducted in the field, addressing the main areas that have been investigated in detail.

This thesis is based on a descriptive study of a cohort of patients undergoing CABG surgery examining correlations between a variety of pre-operative variables with subsequent outcome utilising broad measures of health in its evaluation. The study objectives were formulated to address the following questions:-

- What is the health status in broad terms of subjects prior to CABG surgery ?
- What is the health status in broad terms of subjects following CABG surgery ?
- What aspects of pre-operative health status are associated with changes in health status post-operatively ?
- What are the expectations of benefit from surgery from the patient perspective ?
- How do the patients report the experience of CABG surgery?

In order to answer these questions the study was designed to describe the health status of individuals before and after CABG surgery. Health status was considered in terms of five distinct perspectives namely,

- quantitative estimates of health states as measured by the short-form-36 health assessment questionnaire
- self-rated estimates of angina symptoms using rating scales
- health states as determined by the presence or absence of CHD risk factors
- socioeconomic status, health locus of control and social networks.
- subjective accounts of health and expectation and experience of CABG surgery

Therefore an assessment of a range of factors was planned and an analysis of the nature, if any, of their relationship to the health outcome following CABG surgery. Subjective perspectives on health and accounts of the experience of CABG surgery were used to give a more in depth picture of health than may be apparent from the quantitative measures. The literature pertaining to the methods and the methods used

in the study are presented in Chapters 3 and 4. The results are presented in three separate chapter namely, Chapters 5, 6 and 7 and provide a detailed description of the health status of the subjects before and after CABG surgery and an examination of the inter-relationships of the measured used. A general discussion is presented in Chapter 8 to bring the thesis to a conclusion with recommendations for further areas of enquiry based on the findings of this study.

Chapter 2

2.1 Introduction

The incidence of CHD mortality is documented in annual Government reports on health statistics (Offices of Population Census & Surveys, 1996; Registrar General for Scotland, 1997). The identification of the underlying cause of death is ascertained from death certificates and follows established procedures with diagnostic categories being assigned according to the Ninth Revision of the International Classification of Diseases (ICD) (World Health Organisation, 1977). Clinical events as a result of CHD are classified/coded as acute myocardial infarction (AMI) (code 410), sub-acute coronary disease (code 411) with other manifestations of CHD, for example angina, in codes 412-414. These categories are reported within health statistical reports as ICD 410-414 and, as a grouping, are used to document CHD mortality and morbidity rates and trends.

2.2 CHD Trends

Trends world wide in CHD mortality have been reported by the WHO MONICA Project for males and females, aged 35 to 64 years (Tunstall-Pedoe, Kuulasmaa, Amouyel, Arveiler, Rajakangas et al, 1994). This epidemiological survey of CHD events and CHD risk factors conducted in 38 population groups from 21 countries has compiled an international league table of CHD mortality and morbidity. In the Glasgow MONICA group (n=135,400) CHD mortality was at the top of the league table for females and near the top for males

In Scotland, CHD rates have decreased by approximately 10 percent for both males and females over the last 10 years (Registrar General for Scotland, 1997), the trend can be clearly seen from figure 2.1., which is in contrast to increasing rates in Eastern European and developing countries (Tunstall-Pedoe, 1994).

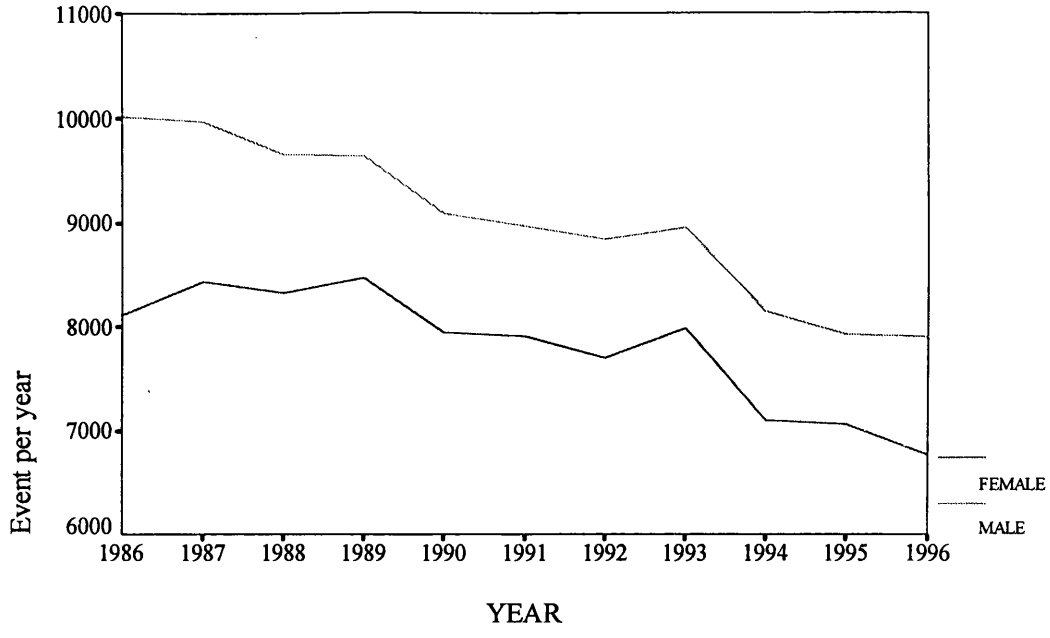

Figure 2-1 CHD mortality rate (events per year) by gender from 1986 to 1996

In Scotland, CHD (ICD 410-414) accounted for approximately 14,000 (7,355 males, 6,658 females) deaths in 1997. Although the figures for males and females are not dissimilar, females were older than men. These deaths represent almost 30 percent of all male deaths and 25 percent of all female deaths with close to 20 percent occurring before 65 years of age (Registrar General for Scotland, 1997).

In the United Kingdom over 150, 000 deaths occur as a result of CHD each year (Kaduskar, Bradshaw and Rayner, 1997). The pattern of mortality according to age and gender is presented in figure 2.2. It illustrates that CHD mortality increases with age, the increase being particularly pronounced at age 65 years and over. Except in the plus 75 age group, female mortality rates are lower than rates for males.

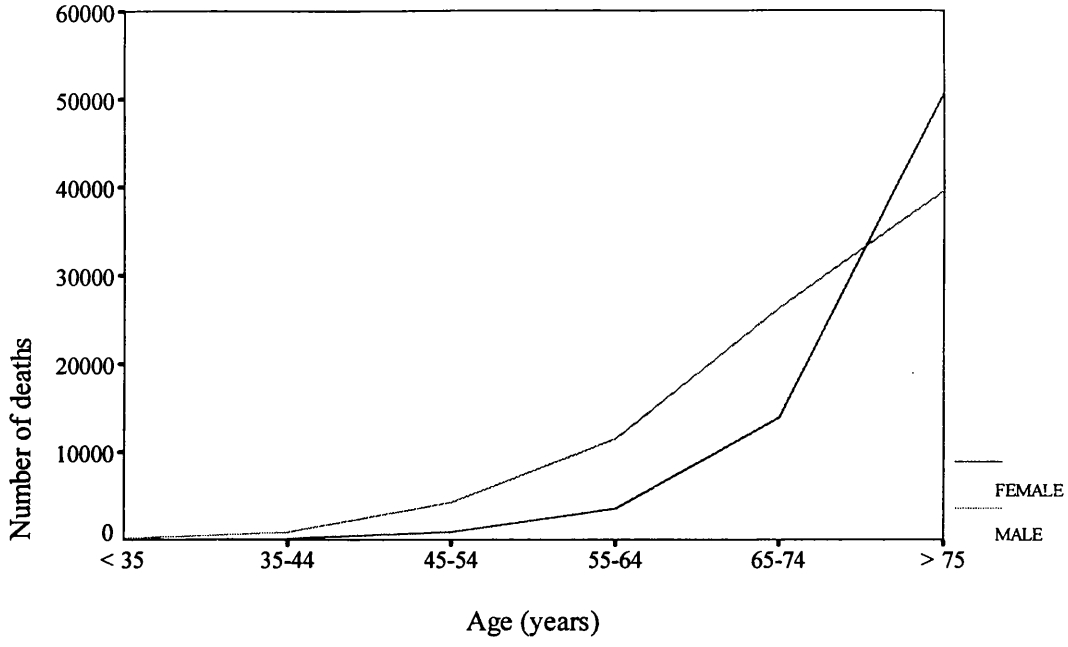

Figure 2-2 Deaths as a results of CHD (ICD 410-414) according to age and gender in the UK, 1995

The prevalence of CHD in the community and the resultant morbidity are much more difficult to establish because such data are not collected on a routine basis although an approximation can be made through epidemiological surveys. In Scotland one of the largest and contemporary surveys (Tunstall-Pedoe, Woodward, Tavendale, A'Brook and McCluskey, 1997), was started in the years between 1984 and 1987. CHD risk status was assessed in a random sample of 11,629 men and women aged 40 - 59 years who were then tracked through record linkage with the Scottish NHS Register (Kendrick and Clarke, 1993) over an eight year period. This register records Hospital Discharge data and is collated by the Information and Statistics Division of the Scottish Common Services Agency (Kendrick and Clarke, 1993). The eight year review of the original cohort (72% completed follow-up) provided information on CHD events, CHD mortality and mortality from all causes. Approximately 20 percent of both men and women had evidence of CHD when initially assessed (based on previous medical history, Rose questionnaire (Rose, Blackburn, Gillum and Prineas, 1982) and a 12-lead ECG) of which 8.2% of men and 5.0 % of women had already been diagnosed. Annual event rates in men were 9.6 per 1000 for all CHD, 3.7 per 1000 for CHD mortality and 8.9 per 1000 for all causes of mortality. The

equivalent rates in women were 4.0, 1.1 and 4.7 respectively. These figures provided a further insight into the impact of CHD to health, the underestimation of the prevalence of the disease in the community and the relatively lower rates in women compared to men in this age range. However, CHD is the leading cause of mortality in women albeit at an older age than men (Register General for Scotland, 1997). It has been estimated that CHD affects approximately 500,000 of the Scottish population of whom 40,000 are quite disabled (OPCS, 1988). The cost to the health service has been estimated at approximately £500 million per annum.

2.3 Cardiovascular Pathophysiology

Atherosclerosis is a pathological process, which has been described as a focal, inflammatory fibro-proliferative response to multiple forms of endothelial injury (Davis, 1990). The "response to injury" hypothesis as the basis for the development of atherosclerosis was formally proposed by Ross and his colleagues more than 20 years ago (Ross, 1986). In essence, it postulated that the normal endothelial repair process, through thickening and scaring, has become the disease process itself. The term atherosclerosis was derived as a means of describing the pathological appearance of the lesions arising inside the affected blood vessels. Its fibrotic encasement of material appeared hard (*skleros*, Greek) and encompassed a soft gruel-like interior similar to porridge (*athere*, Greek) described by Marchand in c1860 (quoted by Aschoff 1924) (Aschoff, 1924). Atherosclerosis has been shown to affect large and medium-sized arteries producing changes in the intima and media of the vessel wall. The lesions develop throughout life and have been found in children (Pathological Determinants of Atherosclerosis im Youth (PDAY) Research Group, 1993) and active healthy men as was demonstrated in post-mortem examination of young soldiers killed in action (Enos, Holmes and Beyer,1953). However, the disease has been shown to be unevenly distributed throughout the arterial system, with the coronary arteries particularly susceptible. Veins are not usually affected in their native state but have shown the potential to succumb to the atherosclerotic process (Grondin, Campeau, Thornton, Engle, Cross et al, 1989) when they are subject to arterial blood pressure levels as has been shown in the saphenous vein grafts employed in CABG surgery.

2.4 The Atherosclerotic Plaque

Atherosclerotic lesions or plaques are the specific foci of the disease process that have been shown to be responsible for subsequent clinical symptoms (Davis,1985). The plaque causes narrowing of the artery lumen, is predisposed to thrombosis and calcification and weakens the arterial wall. Such plaques have considerable accumulation of extra cellular lipids, lipid from within the cells of origin and collagen produced by smooth muscle cells (Davis,1996). By adult life, in developed countries, most individuals will have atherosclerotic plaques that in pathological terms are advanced within the coronary arteries. The dangers of these plaques lie in both their size and in their tendency to fissure and ulcerate. The final pathway to a clinical event has been shown to be related to haemorrhage within the plaque and/ or thrombus formation at the plaque surface related to breach of the surface of the plaque (Davis,1985; Davis, 1990).

2.5 Clinical consequences of Atherosclerosis

2.5.1 Angina Pectoris

The symptoms that are known as angina pectoris have been recognised and described more than 200 years ago. A description of the symptoms dating from that era has been provided by Heberden (Heberden, 1772) who states that 'There is a disorder of the breast marked with strong peculiar symptoms, considerable for the kind of danger belonging to it and not extremely rare, of which I do not recollect any mention among medical authors. The seat of it and sense of strangling and anxiety with which it is attended may make it not improperly be called angina pectoris.' This classic description identifies many of the key elements in the clinical syndrome of angina pectoris. Angina is a symptom classification that is used to describe the pain associated with myocardial ischaemia. It is often initiated through exertion resulting in increased demands on the heart and relieved by rest. Under ordinary circumstances, increases in myocardial oxygen demand are met by an appropriate increase in myocardial oxygen supply. The amount of oxygen used by the heart is directly related to coronary blood flow, the oxygen content of arterial blood and the amount of oxygen extracted from the blood by the heart. Since the oxygen-carrying capacity of the heart cannot be significantly increased unless there is considerable

hypoxia present, the main mechanism by which metabolic demands can be met is through augmentation of coronary flow. However, for patients with CHD, this process is impeded because of the reduced vascular lumen and the syndrome of angina pectoris ensues (Karliner, 1991).

2.5.2 Grading of Angina

Grading of angina relates to physical limitations resulting from any cardiac symptoms, including angina, palpitations, fatigue and breathlessness. Angina chest pain and breathlessness are common symptoms of CHD which have been shown to be strongly related to each other (Cook and Shaper, 1989).

There are four gradings provided by the NYHA system (Criteria Committee of the New York Heart Association, 1974) which are related to impairment in functional status as a consequence of increasing angina symptoms and these are presented in table 2-1.

Table 2-1. NYHA Grading of Angina Pectoris Symptoms

Grade 1: Cardiac disease but no resulting limitations on physical activities. Ordinary physical activity does not cause undue fatigue, palpitations, dyspnoea or angina pain.
Grade 2: Slight limitation of physical activities. Comfortable at rest or on mild exertion. Ordinary physical activity results in fatigue, palpitations, dyspnoea or angina pain.
Grade 3: Marked limitation of physical activities. Comfortable only at rest. Less than ordinary physical activity causes fatigue, palpitations, dyspnoea or angina pain.
Grade 4: Inability to conduct any physical activity without cardiac symptoms. Angina may be present at rest.

2.5.3 Myocardial infarction

Myocardial infarction has been described as occurring when myocardial ischaemia occurs for sufficient time to cause necrosis of a localised area of the myocardium. The exact sequence that leads from coronary atherosclerosis to myocardial infarction is not fully established. However, there is a growing body of evidence to support the interaction between obstructing lesions, vasospasm, platelet activation and thrombotic factors as important mechanisms in the process (Willerson, Campbell, Winniford, Schmitz, Apprill et al, 1984). Post-mortem examination has revealed that acute myocardial infarction (AMI) usually occurs in an area within a coronary artery at the site of a disrupted atherosclerotic plaque (Davis, 1985). It is thought that a rupture or break in the fibrous cap of the atherosclerotic plaque exposes the necrotic core and collagen fibres of the plaque to the overlying coronary blood flow. This has been shown to serve as a focus for thrombus formation and the likelihood of occlusion increased when the underlying plaque already produces significant coronary artery occlusion (Falk, 1983). Most deaths as a result of AMI are sudden and occur within hours of the onset of symptoms. Mortality rates are high (30% early deaths outside hospital, 53% one month survival and 50% one year survival (Tunstall-Pedoe H, 1991). Subsequent mortality has been reported as 5% annually (Public Health Policy Unit, 1996) highlighting the high level of mortality associated with this cardiac event.

2.6 CHD Risk factor Identification and Management

2.6.1 Introduction

The aetiology of atherosclerosis has been described as a response to injury occurring in the endothelium within the arterial system. Punitive agents in this process have been broadly described as 'risk factors'. The term 'risk factor' is widely used to describe those characteristics found in individuals that have been shown in observational epidemiological studies, autopsy studies, metabolic and genetic studies to predispose to the occurrence of CHD. The aetiology and pathogenesis of CHD has been the subject of extensive bio-medical, clinical and pathological investigation over the last 100 years, with major advances in the years since World War II. The risk factor concept is of central importance. In its broadest sense it can be described as a trait that is associated with an increased risk of developing disease. In global

terms risk factor categories cover personal, lifestyle, biochemical and physiological characteristics, some of which are modifiable while others are not.

2.6.2 Identification of CHD Risk Factors

The Framingham Study (Dawber, Meadors and Moore, 1951) began in the 1940's and was designed to generate information that would help in the early detection and prevention of CHD. As stated by Shaper (Shaper, Pocock, Walker, Phillips, Whitehead et al, 1985), it has "become synonymous with the risk factor concept and is the source of much of our knowledge about the risk of CHD in individuals". The study started with a small number of male and female volunteers (n=740) in 1948 and has subsequently grown into a major prospective observational study (Anderson, 1987). Follow-up of the recruits and in some cases their offspring, is still ongoing today and data from the study have given investigators valuable information about the relationship between various risk factors and CHD. The main risk factors for CHD were identified as smoking, hypertension, hyperlipidaemia, diabetes mellitus and family history of CHD (Castelli, 1984). This large study was also notable because it is one of the few large epidemiological studies of CHD that has included women in its cohort.

Several other prospective population studies were initiated in the United States in the 1950's and 1960's and a summary of their results has been published in the final report of the Pooling Project (Pooling Project Research Group, 1978). Together with the Seven Countries Study (Taylor, Blackburn, Keys, Parlin and Vasquez, 1970) factors that predict a major part of the subsequent CHD have been described. These were documented as elevated levels of blood pressure, serum cholesterol, relative weight and ECG abnormalities.

The British Regional Heart Study (Pocock, Shaper, Cook, Phillips and Walker, 1987) screened 7,735 men aged between 40 and 59 years from 24 towns across the United Kingdom and results reported at a mean follow-up period of 4.2 years confirmed the findings in the Framingham study (Castelli, 1984) i.e. hypertension, smoking, hyperlipidaemia, diabetes mellitus, family history of CHD and ECG evidence of CHD. A scoring system based on the analysis of the impact of these risk factors on

subsequent CHD development was calculated. It showed that the top fifth of the score identified 59% of the men who developed CHD over that time period. Because it was not able to predict with more accuracy those who would develop CHD the authors concluded that other factors which had not been taken into account must operate to increase CHD risk. The scoring system also showed that the majority of CHD events did not occur in individuals who had a high value of a single risk factor but rather in those individulas with moderate elevations in a umber of risk factors. This has important implications in terms of the management of CHD risk factors in individuals with multiple risk factors.

The web of causation for heart disease was complex and as more experience of the disease process was gained, it became apparent that more factors than had already been documented had a role to play. While a multitude of factors have been potentially associated with CHD, St George (1983) reviewed the literature and quantified the number of well documented risk factors to be of the order of twenty. Although this review is now dated, the CHD risk factors outlined remain the focus of current clinical practice in the prevention of CHD. These factors are presented in table 2.2.

Table 2-2 CHD Risk factors commonly assessed in clinical practice

Modifiable	Immodifiable
Smoking	Family History of CHD
Hyperlipidaemia	Diabetes mellitus
Hypertension	Male gender
Obesity	Age
Physical inactivity	
Excess alcohol intake	

2.6.3 Influence of CHD risk factor change and mortality

One of the largest contemporary studies that have examined the relationship of changes in the main documented CHD risk factors to reduction in CHD mortality at a population level was conducted in Finland. The extent to which changes in the main coronary risk factors of plasma cholesterol, blood pressure and smoking explain the decline in mortality from CHD was evaluated together with the relative importance

of changes in each of these factors (Vartiainen, Puska, Pekkanen, Tuomilehto and Jousilahti, 1994). Predicted changes in ischaemic heart disease mortality were calculated by a multiple logistic regression model using the risk factor levels assessed by cross-sectional population surveys between the years 1972 and 1979. These predicted changes were then compared with observed changes in mortality statistics.

A total of 14,257 men and 14,786 women aged between 30 and 59 years were randomly selected from the national population register. Total cholesterol levels for men ranged from 6.78 to 5.9mmol/L, diastolic blood pressure 92.8 to 84.2 mmHg and percentage smokers 53% reduced to 37%. In women, plasma cholesterol levels ranged from 6.72 to 5.54 mmol/L, diastolic blood pressure 91.8 to 79.6 mmHg and percentage smokers 11% increased to 20%.

The observed decline in mortality as a result of ischaemic heart disease was obtained from official national mortality statistics. The relative importance of changes in each of the three CHD risk factors in contributing to decline in mortality as a result of ischaemic heart disease was computed. In men, the observed 13% decrease in serum cholesterol predicted 26% decline in mortality from ischaemic heart disease, 9.2% decrease in diastolic blood pressure predicted a 15% decline and a 16% decrease in smoking predicted a 10% decline. In women the observed mortality from ischaemic heart disease was decreased by 68%. The observed 18% decrease in cholesterol concentration predicted a 35% decline in mortality from ischaemic heart disease, the 13% decline in diastolic blood pressure predicted a 31% decline and the 9% increase in smoking predicted an 11% increase.

The study concluded that the reduction in the three CHD risk factors assessed and the changes observed in mortality rates suggested that most of the decline in mortality from CHD could be explained by changes in these three main common risk factors. This Finnish study provided important information on the extent to which the the main modifiable risk factors contribute to CHD mortlaity and because of the large effect of these factors the authors concluded that reduction in elevated levels of these risk factors should be addressed as a priority.

2.6.4 CHD risk factors and socio-economic deprivation in Scotland

The national and international studies such as the British Regional Heart Study and the Finnish study (Vartiainen et al, 1994) reported in section 2.6.3 have confirmed the role of the major CHD risk factors of smoking, hyperlipidaemia and hypertension as important determinants of CHD mortality. One of the problems in collating the results of such studies has been related to the different number and type of CHD risk factors assessed within individual studies. Specifically of importance to assessment of CHD risk in Scotland is the role of socio-economic deprivation, which was not documented in the Finnish study (Vartiainen et al, 1994). However, two large epidemiological studies that have been undertaken in Scotland have included socio-economic deprivation in the assessment of CHD risk factor status, namely the MIDSPAN study (Hawthorne, Watt, Hart, Hole, Smith et al, 1995) and the Scottish Heart Health Study (Smith, Tunstall-Pedoe, Crombie, Tavendale, 1989).

The MIDSPAN study (Hawthorne et al, 1995) has described the epidemiology of cardio-respiratory disease and CHD risk factors in men and women from a large Scottish urban population with high levels of socio-economic deprivation and high mortality rates. Between the years 1972 and 1976 all individuals between the ages of 45 and 64 years who met the residency criteria for two Scottish towns (Renfrew and Paisley) were invited to attend for screening. There was a high response rate of 80% which resulted in inclusion of 7,058 men and 8,353 women. The baseline characteristics reported showed that the majority of men (62.1%) were in social class 3 manual and 4 with less women (44.3 %) in the same social class groups. In terms of socio-economic profile and CHD mortality rates, the authors state that the sample was typical of the general population in the West of Scotland. The prevalence of angina in social class 1 compared to social class 5 increased in men from 11.4% to 27.8% and in women from 15.5% to 19.8%. In effect, there were only small differences in the prevalence of angina between men and women in this population with the exception of more angina in women from social class 1 (15.5% versus 11.4%, and in men, from social class 5 (19.8% versus 27.8%). Age differences may account for the higher prevalence of angina in women from social class 1. The proportion of females (males) currently smoking ranged from 35% (41%) in social class 1 to 56% (70%) in social class 5. The prevalence of angina was more than

double in the Renfrew/Paisley men compared to men in the British Regional Heart Studies (Pocock et al, 1987). The study concluded that a different profile of cardio-respiratory risk and disease was present in the middle-aged males and females from an urban area with high levels of socio-economic deprivation compared to previous population studies conducted in the UK.

Between 1984 and 1986 the Scottish Heart Health Study (Smith et al, 1989) recorded CHD risk factors and lifestyle behaviours in 10,359 men and women aged between 40 and 59 years across 22 districts of Scotland. The districts varied in their standard mortality ratio for CHD in men from 61 in Eastwood to 136 in Monklands. The latter geographical area is associated with a larger proportion of individuals from lower socio-economic deprivation grades compared to the latter area which is associated with a larger proportion of individuals from higher socio-economic deprivation grades.

Cigarette smoking levels showed the greatest variation from 29% to 52% in men and 24% to 51% in women across the different districts. Blood pressure levels were varied but not high across the districts, however, mean plasma cholesterol levels were high but also varied little by district in men, although there was more variation in women, with levels ranging from 6.3 to 7.0 mmol/L in women and 6.1 to 6.5 mmol/L in men. Similarly, body mass index in men and women varied little. When mean levels of the CHD risk factors were collated across the districts and entered into a predictive formula in terms of CHD mortality, cigarette smoking and blood pressure could explain part of the regional variation in mortality but the authors stated that much of the variation remained unaccounted. However, these levels of uncorrected CHD risk factors do provide data for local preventative initiatives and highlight the importance of socio-economic status in relation to CHD mortality.

In a follow-up to the original Scottish Heart Health Study (Tunstall-Pedoe et al, 1997) at an average of 7.6 years, during which time 5754 men had 440 coronary events, 159 coronary deaths and 383 deaths from all causes and of the 5875 women, 177 coronary events, 47 coronary deaths and 280 deaths from all causes. The ranking of all CHD risk factors for these three end points were similar in men and women although the hazard ratios were often higher in women. Classical risk factors such as

smoking, hyperlipidaemia and hypertension ranked better for predicting CHD risk than more recently identified factors such as thrombogenic factors. However, strong prediction of coronary risk was no guarantee of significant prediction of all cause mortality. The analysis undertaken in this study involved unifactorial ranking and comparisons must therefore be interpreted with caution because of the potential interaction of confounding variables and problems of measurement that may occur in such an analysis. While men and women showed different rankings for CHD risk factors there was considerable agreement, for example for all CHD events the same eight factors appear in the top twelve CHD risk factors for both sexes, and for all causes of deaths, the same ten factors. These were unexpected findings because of the heterogeneity of the group in terms of cause of death between men and women. It was suggested that random variation could account for much of the differences in ranking between the genders.

Relationships between factors in observational epidemiological studies are more likely to be as an association rather than causation which is a much stronger relationship. In addition, individual factors may be associated sufficiently closely to cause confounding effects and therefore documentation of independent effects can not be made. Difficulties in obtaining accurate measurements together with patient variability may conceal or minimise true effects.

In this follow-up analysis (Tunstall-Pedoe et al, 1997) the impact of 27 CHD risk factors, covering the full range of classical and candidate factors included in the Scottish Heart Health Study (Smith et al, 1989) were assessed. The authors stressed that their results emphasise that existing CHD is the most powerful of its own predictors and therefore the importance of secondary prevention is further endorsed. At the top of the league table of the 27 risk factors assessed within this study a history of previous angina and previous myocardial infarction was at the top of the league table for both men and women as the strongest predictor of subsequent CHD events and death from all causes.

2.6.5 Conclusions

International, national and regional studies that have screened individuals to identify factors that are related to the subsequent developement of CHD have generated a consensus in terms of the identification of the main CHD risk factors. These are summarised in table 2-2 . The role of the main CHD risk factors with subsequent CHD events will be examined in terms of their relationship to outcome following CABG surgery in section 2.11.

2.7 Surgical intervention in the management of coronary heart disease

2.7.1 Introduction

The objective of surgical intervention in the management of patients with CHD is to directly provide additional blood circulation to the myocardium to compensate for the ischaemic effects of atherosclerotic lesions in the native coronary arteries. In this section a short historical overview of the important developments in the evolution of the procedure are presented and a brief description of the procedure as it is currently performed. A summary of the results of the major studies that have been conducted to evaluate the outcome benefits of CABG surgery is provided, and the evidence of the impact of major preoperative variables on surgical outcome are examined.

2.7.2 Historical perspective

Direct attempts to improve the blood supply to the myocardium began as early as 1935 in the form of causing abrasion to the epicardium to provoke adhesion formation, in the belief that such adhesions would re-direct blood from non-coronary sources to the myocardium (Beck, 1935). More direct attempts followed when Vineberg (1946) reported in the procedure of successfully implanting the freely bleeding end of the internal mammary artery into the myocardium. It was claimed that the procedure produced relief or partial relief of symptoms in the majority of patients and that continued patency with coronary vessels was the underlying reason. Other procedures with the same objective included wrapping omentum, skeletal muscle flaps or lung around the heart. Although a sound physiological basis was claimed for many of these procedures, retrospective review of the evidence failed to demonstrate convincingly improved myocardial perfusion from any of the procedures

(Miller, 1977). Coronary angiography was as yet unavailable to confirm at a vascular level the direct effects of these intervention.

2.7.3 Coronary angiography

Coronary angiography is an investigation that provides direct visualisation of the coronary vascular system. It was introduced to clinical practice in the early 1960s following the pioneering of the technique by Mason Sones (Sones and Shirey, 1962). The investigation involves the injection of a radiopaque dye into the coronary arterial system and real-time cine pictures recorded by a X-ray camera positioned above the supine patient. The resultant visualisation of the anatomy and pathology of the coronary arteries during life has been essential to the development of current CABG surgical techniques. The technique as it was initially developed by Sones (Sones et al, 1962) involved arterial access through the brachial artery. However, more commonly in current practice access is gained via a percutaneous femoral artery puncture as developed by Judkins (1968).

2.7.4 Coronary artery bypass surgery

CABG surgery is a procedure performed in order to provide direct revascularisation of the myocardium. It involves the insertion of one or more bypass conduits, at one end, inserted into the aorta close to the heart, and the other end anastamosed to the native coronary artery distal to the problematic lesion or lesions. An autologous reversed section of a saphenous vein is commonly used as the bypass conduit.

The first reported aorto-coronary bypass grafting used a section of saphenous vein (SV) as the conduit and was performed by Sabiston (1962) although the main workers to carry out the procedure in larger numbers were Garrett and colleagues (Garrett and Diethrich, 1966) and Flavaloro and his group at the Cleveland Clinic Ohio USA (Favaloro, 1983). By the early 1970s bypass grafting using SVs became an important therapeutic intervention in the treatment of chronic CHD. The procedure continued to gain acceptance and further refinements made by Green, Stertzer and Reppert (1968) evolved when he reported anastamosing the internal mammary artery (IMA) as a pedicle graft to the native coronary artery. Both SV and IMA grafts continue to be used today in the procedure to bypass diseased coronary

arteries and arterial conduits from other parts of the body are being employed. Often a combination of one IMA graft together with one or more SV grafts are used to achieve revascularisation of the myocardium. Additional technical advances have made the procedure safer which include better methods of myocardial protection during surgery, advances in intensive care support in the immediate post-operative recovery phase and improved medical therapy, particularly for patients with unstable angina (Wheatley, 1986). Together these advances have made surgical myocardial revascularisation an important intervention in the management of individuals with CHD with relatively low but well defined morbidity and mortality.

2.7.5 Indications for CABG surgery

CABG surgery as an intervention for the management of CHD is considered when obstructive or partially obstructive lesions have been demonstrated to be present in the coronary arterial tree. Angiographic studies are a prerequisite to provide details of the locality and severity of the lesions and myocardial function (Wheatley, 1986). It is conventional to classify extent of significant coronary stenosis as single-vessel, double-vessel or triple vessel related to the number of arteries diseased. Disease of the left main descending coronary artery is usually noted as a separate category because it has been shown to be a strategically important artery. A high-grade proximal stenosis of this vessel has been associated with a increased risk of premature death (European Coronary Surgery Study Group, 1982). The use number of diseased coronary arteries to categorise severity of disease has been criticised because it provides no indication of the extent to which the myocardium is rendered ischaemic either at rest or during activity (Selzer, 1982).

An assessment of the severity of the angina symptoms is also made according to the NYHA classification (Criteria Committee of the New York Heart Association, 1974) which groups symptoms according to functional limitations into four categories as outlined in table 2-1 in section 2.5.2. However, the severity of angina chest pain symptoms has not been shown to relate directly to the extent of stenosis in atherosclerotic lesions (Cohn, Harris, Barry, Rosati, Rosenbaum et al, 1981) so in practice both clinical and angiographic evidence of disease are used to estimate disease pattern and severity. Indications for CABG surgery are judged on the basis of

the comparative benefits of the operation, relative to no treatment, medical treatment or treatment by percutaneous transluminal angioplasty (Maley, 1986; Califf, Harrell, Lee, Rankin, Hlatky et al, 1989).

2.7.6 Trends in rates of surgery

A register of the number and type of cardiac surgical procedures performed in the United Kingdom has been compiled since 1977 (Report of the Great Britain and Ireland Cardiac Surgery Register, 1996). The figures published within these annual reports have documented a ten-fold increase in CABG surgery procedures from a figure of approximately 3000 a year in 1977, either as a single procedure or together with another cardiac procedure, to almost 25,000 operations in 1995. There was a marked regional variation in the number of procedures performed and operation rates per million population vary from as low as 189 operations per million population in the south west of England to 478 operations in Northern Ireland. In Scotland, the rates of operations are among the highest in the UK, with a rate of 448 operations per million population in the year 1995. Although these figures are increasing they still lag behind experience in the US where in the year 1994 over 1000 operations per million population were performed (Edwards, Clark and Schwartz, 1994a).

2.7.7 Evaluation of the CABG surgery

It was recognised at an early stage in the development of this new surgical procedure that evaluation of its benefits and adverse effects should be a concurrent consideration. Consequently a large number of studies have sought to evaluate the probability of death, freedom from adverse outcome events. In addition, identification of the factors that operate against optimal outcome have been the subject of observational or database studies and randomised controlled trials conducted both in the short and long term. Standardised periods for reporting mortality are commonly 30-day post surgery and subsequently annually (Clinical Outcomes Working Group, 1998). The major studies are reviewed in sections 2.8, 2.9, 2.10, 2.11.

2.8 Evaluation CABG surgery compared to medical management

2.8.1 Introduction

Three major randomised trials have been conducted to test the mortality and morbidity differences between a strategy of initial CABG surgery with one of initial medical therapy. Although the studies are dated they are important because current practice is still influenced by the results and no subsequent trials of this design or with similar numbers have been conducted.

2.8.2 The Veterans Administration Study

In the early 1970s, the Veterans Administration (VA) (Murphy, Hultgren, Detre, Thomsen and Takaro, 1977) undertook a multi-centred, prospective randomised study to determine the potential benefits of CABG surgery using saphenous vein grafts. This study was the first large scale randomised trial designed to evaluate the benefit of CABG surgery compared with medical therapy in the treatment of patients with stable angina pectoris. The study was conducted in the years 1972-74 and 18 years of follow-up data have been collected over that time period on an initial cohort of 686 male subjects (The Veterans Administration Coronary Artery Bypass Surgery Cooperative Study Group, 1992).

There was a relatively high operative mortality rate reported in the study as presented later in table 2-3. Early follow-up data on patients failed to demonstrate a statistically significant benefit between the medically and surgically treated groups except for a sub-group of patients with LAD disease who had surgery. This may have been the effect of the initial relatively high operative mortality. However, the patients who were angina-free were significantly higher in the surgical group during the first five years of follow-up. Rates of freedom from angina symptoms for the medicine and surgery treated groups were at one year (3% vs 22%, $p<0.001$), at five years (4% vs 12%, $p<0.001$) and at ten years (6% vs 5%, ns).

Longer term follow-up has been reported at seven, 11 years and 18 years. Freedom from non-fatal MI was significantly greater in the medically treated group (68% vs 56%, $p=0.015$) although the probability death as a result of myocardial infarction was similar in the two groups. The results have shown that surgery conferred statistically

significant survival advantage over medical treatment at 7 years (77% vs 70%, p=0.043) but beyond this time period the survival benefit diminished and there was no significant difference in overall survival (58%) between the surgical and medically treated groups at 11 years. The overall conclusions reached by the investigators were that two groups of patients gained greater benefit from surgery, namely; patients with LAD disease and those with extensive CHD and reduced left ventricular function although these benefits were not maintained beyond 11 years after surgery.

There were methodological issues with the study which have limited the findings. In particular, there were a large number of patients (40%) initially randomised to medical therapy who by ten years had undergone CABG surgery, although their status in the data analysis remained as medically treated described as 'on an intention to treat basis'. This could potentially underestimate the benefits of surgery. A possible explanation for the diminution of favourable results between 7 and 11 years and beyond may be late graft occlusion. It was not possible to evaluate in more detail the impact of a range baseline variables because limited data were reported. Specifically, number of coronary vessels diseased and LV function, NYHA angina class, previous history of myocardial infarction were only estimated in a sub-group of 102 patients.

2.8.3 The European Coronary Surgery Study

The European Coronary Surgery Study (ECSS) (European Coronary Surgery Study Group, 1982) was conducted between 1973 and 1976 and included a total of 768 male patients, ages less than 65 years. At five year follow-up survival was higher in the surgically treated group than the group assigned to medical treatment (92.4% vs 83.1%, p=0.001). Beyond five years there were greater increase in deaths in the surgically treated group so by 12 year follow-up there was no survival difference between the two groups.

2.8.4 Coronary Artery Surgery Study

Coronary artery surgery study (CASS) 1975-1979 (Alderman,1990) was the most recently conducted study with a similar number of subjects (n=780) as recruited to

the previous studies outlined in sections 2.8.2 and 2.8.3. The primary objective of the study was to compare a strategy of initial surgery versus initial medical therapy. Sixteen percent of conduits used were internal mammary artery grafts whereas in the VA (Murphy, 1977) and the ECSS (European Coronary Surgery Study Group, 1982) studies virtually all grafts were constructed with the saphenous vein. However, the results were in agreement with the other two studies in that there was no significant difference in survival benefit or occurrence of myocardial infarction between medical and surgical groups at 10 years in the whole population. The high risk patient with reduced EF and those with triple-vessel disease should gain greater benefit from surgical intervention particularly in the first five years.

2.8.5 Conclusions

Randomised controlled trials provide a rigorous approach to the evaluation of the effect of one treatment compared to another. A summary of the time period in which the studies were conducted and mortality rates at 30 days and one year following the procedure are presented in table 2-3.

Table 2-3. Mortality rates at 30 days and one year following isolated CABG

Study	study era	30 day mortality	one year mortality	Isolated CABG
EECS	1973-76	3.20	4.51	394*
CASS	1975-79	1.50	1.90	390*
VA	1972-74	5.90	7.10	332*

*Numbers initially randomised to CABG surgery on an intention to treat basis

Frequently these studies are based on narrowly defined population groups and as such may have limited applicability to general clinical practice. In addition, a review of these studies (Dargie, 1992) points out that there have been advances in both medical therapy and surgical interventions that have changed current practice to such an extent that their relevance is limited. In particular the increase in the practice of using the IMA as a conduit in the CABG procedure and the increased severity of disease present in patients that are treated are likely to limit the implications that these studies have for practice to-day. The interpretation of the status of patients who

had initially been randomised to medical treatment and changed later to surgical treatment differed, in some cases they were still considered to be receiving medical therapy while in others their status was that of surgical treatment. In the former situation the benefits of CABG surgery could be underestimated.

It has been postulated that surgically treated patients with initial immediate relief of ischaemia may not receive the same attention to modify atherogenic risk factors as do patients with angina who are medically treated (Alderman, 1996), although it now known that atherosclerosis continues in both grafted and non-grafted arteries (Grondin, Campeau, Thornton, Engle, Cross et al, 1989; Lytle, 1994).

In a systematic overview of the three large randomised studies discussed in the previous sections and four smaller studies (Yusuf, Zucker, Peduzzi, Fisher, Takaro et al, 1994) of CABG surgery compared to medical therapy, individual patient data were collected on a total of 1324 patients who were initially assigned to CABG and 1325 to medical therapy. At ten years there was improvement in survival of 4.26 months in the surgically treated group compared to medical treatment. The results therefore demonstrate a very modest improvement in survival as a result of CABG surgery. The limitations of the individual large randomised trials, as discussed above, such as cross-over to surgical intervention by the medically treated group yet patient status remaining as medically treated and therefore influencing the results of the surgical treated group.

Extension to survival was examined in the surgically treated group compared with the medically treated group who had been stratified into three risk categories according to prognostically important clinical and angiographic risk factors such as severity of angina, abnormal exercise test, LAD disease and LV function. Extension to survival for those in the highest risk category was 8.8 months (SE 5.4), $p<0.003$, a very modest improvement, although statistically significant. In the individual studies presented in the previous section such categories of patients have been shown to gain greatest benefit from CABG surgery. Even lower benefits were gained in the moderate and low risk categories, with the limited data for the low risk subjects showing a non-significant trend towards greater mortality with CABG surgery. The analysis concluded that an overall strategy of initial CABG surgery was associated

with lower mortality at 10 years post intervention than one of medical management, with delayed surgery if necessary in the highest risk patients with stable CHD.

2.9 CABG graft outcome assessment

2.9.1 Graft Outcome: Veins

Early vein graft occlusion in the first days after surgery is estimated to occur in 10 per cent of venous grafts rising to between 15 and 30 per cent by one year following surgery (Milgalter, Fraser, Secker and Pavis, 1992; Liem, Hasenbos, Booij and Gielen, 1992). By 10 years, approximately one-third of vein grafts that were patent at one year after surgery have become occluded, one-third demonstrate significant atherosclerosis and the remainder appear unchanged (Liem et al, 1992). Early closures have been attributed to surgical manipulation of the vein graft during harvesting and implantation resulting in endothelial damage and subsequent platelet and fibrin deposition (Rosen, Geraci, Ash, McNiff and Moskowitz, 1992). Beyond the first year after surgery, in grafts that have become occluded, there is evidence that this occurs as a result of atherosclerosis (Liem et al, 1992) a process that also progresses in the native coronary arteries.

2.9.2 Graft Outcome:Arteries

In contrast atherosclerosis has been observed rarely in the internal mammary artery conduit. A retrospective study (Edwards, Clark and Schwartz, 1994b) compared survival rates in patients with venous only grafts and patients who had at least one IMA used in the CABG procedure operated over a 4 year period. The results showed that in all but the lowest risk groups where there was no difference in survival between the two groups, the IMA group was independently associated with improved survival. A longer term outcome study of 10-year angiographic follow-up examined patency rates of IMA grafts (n = 855) and vein grafts (n = 1445) to the LAD. The results showed a highly significant maintenance in patency of the IMA compared to venous conduits (96% v 81.1%, $p<0.0001$) (Loop, 1996). The survival rate at 10 years was 86.6% (IMA group) and 75.9%(venous only group) which was statistically significant on univariate analysis. Survival with freedom from any cardiac event was significantly improved in the IMA group compared to the vein only group (58.9% v

53.3%, p <0.05). The study concluded that the anastamosis of IMA conduit to the LAD coronary artery is preferable whenever indicated and technically feasible.

2.9.3 Summary of Type of CABG Graft and Outcome

The studies that have examined the fate of both venous and arterial grafts have been conducted within the context of observational studies (Milgalter et al, 1992; Edwards et al, 1994b; Loop, 1996). As such the interpretation of the results must be undertaken with caution in that there may be factors that are different in the characteristics of the groups studied, for example higher levels of lipids or increased smoking rates that may explain the observed changes in the different vessels over time. In addition, suitability of the conduits may cause selection bias because they help to determine choice and site of insertion of vessel used. However, studies which have examined the fate of arterial grafts and vein grafts within the same individual (Loop, 1996) have ensured that the environmental factors are the same for both types of grafts. Technical factors may affect suitability of particular grafts for specific situations such as using the IMA to bypass the LAD. Therefore, although the body of evidence supports the view that the IMA has improved patency rates over venous conduits, other factors likely to affect graft fate should also be considered.

2.10 Symptomatic outcome after CABG Surgery

Major relief in angina symptoms has been reported to occur in up to 95 per cent of patients with chronic stable angina (Sergeant, Lesaffre, Flameng, Suy and Blackstone, 1991; Yusuf, 1988; Cameron, Davis and Rodgers, 1995). In the coronary artery surgery study (CASS) registry, data for nearly 25,000 (n=24,959) patients with CHD has been collected including clinical variables, medical or surgical management and mortality and morbidity outcomes (Loop, 1985). This observational study has provided important outcome data on numerous subsets of patients.

In a consensus statement (Kirklin, Naftel, Blackstone and Pohost, 1989) survival and event free survival were examined across a number of institutions both in Europe and the United States, over varying time periods. This study was based on observational analysis of surgical intervention, particularly mortality rates, over a 15 year period

from the mid-1970s to the late 1980s in seven institutions. The overall analyses included data on 13,078 patients with 30-day mortality rates reported as 1.6% of total population and 90.8% of patients surviving to five years or more after CABG for the first time as a single procedure. For those institutions with a longer follow-up period data are presented for longer term survival and event free survival. The survival at 10 years was 80% which was comparable both to an age, gender and race matched general population survey, although by 15 years, survival had diminished to 58% which was distinctly lower than the matched general population. The hazard function for risk of death per 1000/month overall after primary isolated CABG was 4.0 at one month, 1.0 at one year, 2.1 at 5 years, 3.3 at 10 years and 7.9 at 15 years. The hazard function for risk of death per 1000 at each moment in time (deaths/month) and for ischaemic events in one centre (1971-1989) was respectively 3.4 (7.9) at one month, 0.86 (4.4) at one year, 1.2 (4.8) at 5 years, 3.3 (12) at 10 years and 7.9 (30) at 15 years.

The study reported, in the overall patient population, that 77% of patients were free from ischaemic events (return of angina, MI or sudden death) at 5 years after surgery. Even after 10 years, 50% of patients remained event free, although by 15 years or more, only 15% of patients remained free of ischaemic events. In the five year period beyond 10 years, there was a significant increase in the rate of symptom return. In the European centre event free survival was reported on 5,880 procedures as 93% at one year after surgery (after taking into account perioperative deaths) which is a very low rate compared to studies discussed in the later in this section.

Particularly in the early years of this time period, patients selected for surgery were likely to have less severe angina and disease, being similar to levels in the CASS study subjects (Alderman et al, 1990) and therefore a low risk population. Such patients are likely to have a better outcome than those with greater severity of disease that undergo CABG surgery in current practice. In addition, the survival benefits of medical management or angioplasty have not been addressed for a similar patient group so it is not clear what additional benefits surgery may confer.

In another observational study conducted in the United States, follow-up over a 20 year period, was undertaken for 8,971 patients who underwent CABG surgery between the years 1970 and 1973 (Cameron et al, 1995). Angina recurred in 24 % of patients in the first year after surgery and in 40% of patients by the sixth year. The significant pre-operative predictors of return of angina, using multivariate analysis, were minimum severity of CHD, pre-operative angina, use of vein grafts, incomplete revascularisation, female gender, smoking and younger age. The return of angina in the first year post-surgery was shown to be associated with more frequent myocardial infarction ($p=0.04$) and greater need for re-operation ($p=0.03$) but over a six year follow-up period did not affect survival rates. Other investigators have reported freedom from angina rates at five years and 10 years after surgery rates of 85% and 60 % respectively (Yusuf, 1988).

In a study conducted in the United Kingdom comparing CABG surgery to PTCA (Pocock, Henderson, Rickards, Hampton, King 3rd et al, 1995), the percentage of subjects in the CABG surgery group ($n=481$) with any level of angina symptoms at one and three years was 10% and 22% respectively. This was similar to the 10.9% return of angina symptoms reported after one year in subjects ($n=474$) following CABG surgery within a randomised controlled trial comparing angioplasty to CABG surgery (CABRI Trial Participants, 1995). However, in another study (Brandrup-Wognsen, Berggren, Caidahl, Karlsson, Sjoland et al, 1997), assessment at two years after surgery reported that 42% of the subjects ($n=1291$) had chest pain. The self-reported chest pain correlated well with chest pain during exercise test but not with signs of myocardial ischaemia. The main independent predictors of chest pain identified were severity of pre-operative angina ($p<0.001$), younger age ($p<0.001$) and duration of symptoms ($p=0.005$). These studies would support the investigation of chest pain symptoms following CABG surgery in order to establish their origin.

2.11 CABG surgery outcome in relation to patient characteristics

2.11.1 Introduction

A large number of prospective studies have been undertaken in order to examine the relationship between a range of preoperative factors and outcome following CABG surgery. Multivariate statistical analysis techniques have been used to assess the

strength and dependence of the relationship between such pre- and peri-operative variables and outcome. The following sections have examined in more detail the influence of the main determinants of outcome following CABG surgery that have been identified in the literature.

2.11.2 Gender

In the United Kingdom, CHD is the leading cause of death in women aged over 65 years and a major contributor to mortality and morbidity in younger women (Offices of Population Census & Surveys, 1996). Although the disease is less common in women before the menopause, its incidence increases steeply after the menopause, so that by the sixth decade of life, rates of CHD are almost equal in women and men (Lerner and Kannel, 1986). Although CABG remains the most common form of myocardial revascularisation, there has been debate in relation to a possible selection bias against women in terms of angiographic investigation and selection for CABG surgery (Ayanian and Epstein, 1991; Limacher, 1996). A review of contemporary practice in Scotland suggests that women are under-referred for angiography but when this investigation has been performed, then women do receive appropriate referral for CABG surgery (Public Health Policy Unit, 1996).

In the United States over the ten year period 1980–1990, a national database of records of approximately 81,000 patients undergoing CABG surgery showed a trend for increased surgery in women (17% v 27.0%, $p<0.005$) (Edwards et al, 1994a). A summary of studies conducted in different countries, over a wide time, period are presented in table 2-4.

Table 2-4. CABG Surgery (single procedure) 30 days mortality rate by gender

Study	Subjects				Mortality		
	M	F	Period	Country	M	F	pvalue
Weintraub et al,	2792	532	1974-1979	US	1.0	1.3	NS
1993	2793	694	1988-1991		2.7	5.4	0.009
Hammar et al 1997	3326	607	1980 1989	Sweden	1.7	3.0	NS
Brandrup-Wognsen	1727	402	1988-1991	Sweden	2.8	7.0	<0.001
et al, 1996					2.8	4.6	<0.05
Barbie et al, 1994	362	120	1991-1993	UK	1.4	4.2	0.14

The major trend demonstrated in these studies was that 30-day mortality rates for CABG surgery, as a first procedure, was statistically significantly higher for females than males in the more recent era of surgery although in the earlier surgical era early mortality rates were not statistically different between males and females (Hammar Sandberg, Larsen and Ivert,1997; Risum, Abdelnoor, Svennevig, Gullestad, Bjornerheim et al, 1997). The higher operative status of women has been estimated as almost twice that of men in a large multi-institutional database of CABG surgical experience in approximately 81,000 cases (24.6% female) including re-operations and emergency procedures (Edwards et al, 1994a).

Studies have been conducted to investigate the role of preoperative risk variables in determining differences in outcome between males and females. In a Swedish prospective follow-up study of CABG surgery as a first and single procedure (Brandrup-Wognsen, Haglid, Karlsson, Berggren and Herlitz, 1995), the presence of preoperative CHD risk factors of age, hypertension and diabetes mellitus was assessed in 1727 males and 402 females. These CHD risk factors were statistically significantly higher in females than males, although there were no differences in the urgency for operation between males and females. However, the mortality rates at 30 days after surgery were statistically higher in females than males (7.0% v 2.8%, $p<0.001$). At two year follow-up there was no statistically significant difference in mortality between males and females, and the authors concluded that females are more at risk of early death following CABG compared to males, but that the long-term benefit was similar in men and women.

A smaller prospective observational study was conducted in the UK to examine the differences in CHD risk factors in 362 males and 120 females undergoing CABG and their relationship to in-hospital mortality (Barbir, Lazem, Ilsley, Mitchell, Khaghani, 1994). The results showed that women were older than men (63 years vs 60 years, $p<0.001$), were more frequently hypertensive (47% v 33%, $p<0.01$), had a higher rate of diabetes mellitus (21% v 10%, $p<0.005$), had a higher mean levels of total cholesterol (7.3mmol/L v 6.5 mmol/L, $p<0.002$) and more frequently had a family history of premature CHD (45% v 31%, $p<0.0006$). However, more men were cigarette smokers (67% v 45%, $p<0.0001$). In this study, no statistically significant differences were found between males and females in respect of BMI and previous history of myocardial infarction. Mortality rates at 30 days following CABG surgery were 1.4% in males and 4.2% in females, a difference that was not statistically significant. Univariate analysis was performed using the above CHD risk factors in the model and a preoperative history of diabetes mellitus was shown to be a significant predictor of mortality ($p=0.03$). None of the other CHD risk factors assessed showed statistically significant effects on mortality. The finding was that women had increased early mortality rates compared to men but in the long-term the mortality rates in both sexes was similar. This pattern has been noted by other investigators (Risum et al, 1997). Body size was not shown to account for the differences in operative mortality observed between males and females (Christakis, Weisel, Buth, Fremes, Rao et al, 1995). The general consensus from the literature has been that women are at higher risk of adverse outcome following CABG surgery.

2.11.3 Age

The effect of increasing age on the outcome following CABG has been the subject of detailed investigation, this being of particular relevance as surgery is increasingly performed on older patients. Perioperative survival of patients undergoing CABG was examined for subjects ($n=1464$) aged 40 to 65 and for subjects ($n= 663$) aged 75 years and over (Khan, Kupfer, Matloff, Tsai and Nessim, 1992). The 30 day after surgery mortality rates were significantly lower in the younger group than in the elderly group (1.8% vs 7.5%, $p<0.001$). The length of postoperative stay was significantly longer in the elderly (16.5 days vs 10.8 days $p<0.001$).

In a small study (Mick, Simpfendorfer, Arnold, Piedmonte and Lytle, 1991) evaluated early and three year outcome following CABG (n=142) and PTCA (n=52) in octogenarians. Those selected for CABG had significantly poorer angina class (III and IV, 92% vs 67%, $p<0.001$), more three-vessel disease (34% vs 77%, $p<0.001$), were more likely to have impaired LV function (82% vs 65%, $p<0.034$). In general revascularisation in elderly patients was considered to be complicated by a higher incidence of extensive CHD. Significant morbidity (including MI and stroke) was more frequent in the elderly with up to 5% of elderly patients experiencing MI or stroke after surgery and PTCA. Hospital mortality was of the order of 5-10% in octogenarians following revascularisation procedures. The study concluded that effective relief of symptoms and excellent long term survival could be achieved after the revascularisation procedure. Octogenarians with severe CHD and advanced symptoms should be considered for revascularisation despite advanced age. The study did not document the extent to which co-morbid conditions existed in the population.

Patients undergoing CABG surgery in the 1990's have been shown to be older and with more concomitant disease (Christakis, Ivanov, Weisel, Birnbaum, David et al, 1989). In a study of 13,625 patients undergoing CABG surgery, the influence of age in predicting operative complications and mortality was evaluated (Weintraub, Clements, Ware, Craver, Cohen et al, 1991). Most patients were aged between 40 and 79 years (97.6%) and results were based on analysis of the study population in decade intervals. The overall trend in the study population showed a statistically significant increased rate of hypertension, congestive heart failure, three-vessel and LAD disease, more severe classes of angina ($p<0.001$) as age increased, in ten year intervals. Diabetes mellitus was noted to be more common as age increased until the age of 80 years when thereafter the prevalence decreased. This latter trend may be a feature of the relative contraindication for CABG surgery in octogenarians with diabetes mellitus. On multivariate analysis, age was shown to be an independent correlate for the major complications of neurological events, wound infections and death. Operative mortality was lower for patients under the age of 50 years compared to that observed in patients aged over 70 years (1.8% vs 7.4%, $p<0.0001$). The literature has identified the higher risk status for surgery in the elderly but also

recognises that younger age (less than 40 years) also has an excess risk of complication which has been attributed to the presence of high levels of CHD risk factors (Wagner, Ennker and Hetzer, 1996). In summary, both advanced age and younger age are both associated with increased level of CHD risk factors and likelihood of complications after CABG surgery.

2.11.4 Smoking

Cigarette smoking is the most important modifiable risk factor for CHD with a highly attributable risk in all ages in both men and women (Doll, Peto, Wheatley, Gray and Sutherland, 1994). The association between smoking and risk of first myocardial infarction has been shown to be dose related and independent of other CHD risk factors (Nyboe, Jensen, Appleyard and Schnohr, 1991). Smoking has been shown to be a strong risk factor for a first myocardial infarction and for fatal and non-fatal recurrences (Shaper, Pocock, Walker, Phillips, Whitehead et al, 1985).

Within three years, individuals with established CHD who stop smoking have been shown to reduce their risk of further CHD events to the level of individuals with CHD who had never smoked (Wilhelmsson, 1988). Many strategies have been used to help people stop smoking and the results reported in smoking cessation trials vary widely. A meta-analysis of controlled trials identified that personalised smoking cessation advice and assistance reinforced on multiple occasions from several sources gave the highest success rates (Haddock and Burrows, 1997; Kallke, Ballister, De Friese and Brekke, 1988). Brief, frequent interventions have been shown to be most likely to achieve smoking cessation (Lennox and Taylor, 1995).

In a study designed to assess the effects of cigarette smoking on the incidence of non-fatal myocardial infarction, and to compare the effect of tar content from different types of manufactured cigarettes, 14,000 cases and 32,000 controls (non-smoking relatives) were examined (Parish, Collins, Peto, Youngman, Barton et al, 1995). Cases were survivors of myocardial infarction recently discharged from hospital. There was between a two- and five-fold difference in rates of myocardial infarction between smokers and non-smokers with the higher rates in the younger age groups. These differences were still apparent after standardisation for age, gender and amount

smoked. When comparisons were made between rates of non-fatal myocardial infarction and tar content in the smokers there was a small non-significant increase in events with the higher tar cigarette group. This difference was far outweighed by the effect of smoking any type of cigarette compared to the non-smoking group. The authors concluded that far more risk is avoided by not smoking than by changing from one type of cigarette to another. The study was observational and retrospective in design and the choice of control group may introduce some bias because relatives may have similar characteristics to the cases in terms of other major determinants of health such as social class and genetic predisposition.

In a study designed to examine the referral patterns for CABG surgery in smokers and non-smokers, 7,735 men aged 40 to 59 years were screened from across 24 towns in the UK. In total 3185 men were identified as current smokers (Morris, McCallum, Walker, Whincup, Ebrahim et al, 1996). A comparison was made between smoking status, recall of a diagnosis of ischaemic heart disease (IHD) and CABG surgery referral. Of the men who did recall a diagnosis of IHD, smokers were less likely to undergo CABG than ex-smokers (9.4% v 3.5%, p=0.026). The authors concluded that continued smoking after a diagnosis of IHD resulted in lower rates of CABG surgery and that a complex interplay existed between the men's experience of health, the decision to stop smoking, and the willingness of doctors to consider CABG surgery.

Studies that have been conducted to examine the effect of cigarette smoking both in current smokers and in ex-smokers have shown different effects over time. A study reviewing approximately 3000 (n=2916) patients having first time CABG (Utley, Leyland, Fogarty, Smith, Knight et al, 1996) examined smoking status in relation to operative morbidity and mortality. Analysis based on groups of smokers and non-smokers matched for age and gender showed that there was no significant difference in the incidence or magnitude of preoperative or operative factors except that recent myocardial infarction was more common in smokers. There was no difference in mortality and morbidity at CABG surgery at the 95% confidence interval. In another study of longer term outcome, more than 2,000 (n=2121) consecutive patients undergoing coronary angiography prior to CABG surgery were reviewed (Herlitz,

Haglid, Albertsson, Westberg, Karlson et al, 1997). Approximately 10% of these patients admitted smoking. There was no significant difference in operative mortality rates between smokers, ex-smokers or non-smokers. However, at five years after surgery, the mortality rates were 18.8% v 13.6% v 12.5%, respectively ($p<0.0001$), demonstrating that continued smoking was a strongly significant predictor of five-year mortality.

2.11.5 Hypertension

There is strong evidence that links hypertension and CHD mortality, the association confirmed in studies conducted more than 20 years ago by Reid, Hamilton, McCartney, Rose, Jarret and Keen (1976), and Swales (1984). These findings were confirmed in large prospective observational studies investigating the relationship between CHD risk factors for CHD mortality. The earliest of these was the Framingham study (Castelli, 1984) that monitored a population sample, aged over 30 years, throughout a period of 24 years. Both diastolic and systolic blood pressures were measured at regular intervals over the duration of the study. Subjects who were identified as hypertensive at the outset suffered considerably higher rates of CHD and the rate of CHD increased as the level of blood pressure increased. Systolic blood pressures greater than 160mm Hg or diastolic blood pressures greater than 95 mmHg were shown to have between a two and three fold risk of CHD. Borderline elevated systolic blood pressures between 140 and 159 mmHg or diastolic blood pressures between 90 and 94 mmHg had a 50 percent increased risk of CHD. Thus, the higher the blood pressure the greater the risk of a subsequent cardiovascular event. In addition, in a separate sub-group analysis in individuals who had suffered a myocardial infarction, hypertension increased the risk of re-infarction and mortality as the result of a coronary event (Wong, Cupples, Astfield, Levy and Kannel, 1989). A similar relationship between elevated blood pressure and CHD risk was documented in the British Regional Heart Study (Shaper et al, 1985), a prospective observational study conducted in 7,735 middle aged men, over a seven year period. A range of the main CHD risk factors were assessed at baseline and intervals throughout the study and CHD events documented and the relationship of event rates correlated with CHD risk factor levels.

2.11.6 Hypertension and CABG surgery

In a two year prospective study mortality and morbidity rates were assessed in patients undergoing CABG surgery with a history of hypertension (n=777) and non-hypertensive patients (n=1348) (Herlitz, Brandrup-Wognsen, Haglid, Hartford, Emanuelsson et al, 1996). The hypertensive group was older, had a higher proportion of females and more frequently had a history of diabetes mellitus, obesity and intermittent claudication. However, the smoking rate and previous CABG surgery were lower in the hypertensive group. There was a small non-significant increase in 30-day mortality in the hypertensive patients but a statistically significant ($p<0.05$) increase in mortality at two years after CABG surgery. On multivariate analysis, a history of hypertension was not an independent predictor of mortality during the two years of follow-up. There was a different pattern of CHD risk factors in the hypertensive patients and it is possible that such a profile was contributing to the increased risk and that hypertension was a marker for this increased risk and subsequent poorer prognosis following surgery.

In the European Coronary Surgery Study (European Coronary Surgery Study Group, 1982), a history of hypertension when considered in univariate analysis of outcome was shown not to influence the survival rate between the medical and surgically treated groups. However, within each group there was a difference in survival related to a history of hypertension. After two years follow-up, there was approximately 96% survival rate in the non-hypertensive group compared to 90% survival rate in the hypertensive group. This may be a result of a small number of hypertensive patients in each group but when analysis was performed according to hypertensive state, a trend of diminished survival was observed. No statistical significance testing was performed and the numbers of surgically treated subjects with hypertension was small (n=69).

Quality of life was examined, using a series of three assessment tools before and at several time points up to two year following CABG surgery in a convenience sample of hypertensive and normotensive patients (Sjoland, Hartford, Caidahl, Karlson, Wiklund et al, 1997). In both groups, quality of life as measured by the instruments selected for use in the study improved at three months, one and two years. The

degree of improvement was statistically significantly lower ($p<0.05$) in the hypertensive group at three months and at two years after CABG surgery. In addition, the physical activities score was significantly lower in the hypertensive patients compared to the non-hypertensive patients ($p<0.01$). It was not clear from the data presented what the mechanism was for this effect. In particular it was not specified if hypertensive patients at the outset continued to experience elevated blood pressure. The lower quality of life as measured by the scales in the study may be a direct effect of anti-hypertensive therapy itself rather than a poorer outcome as a result of surgery. The adverse effect of some anti-hypertensive agents has been thought to relate to poor compliance rates. However, in a review of the benefits of drug treatment, the authors concluded that there was compelling evidence that the risk of CHD events and stroke being significantly reduced (Collins and MacMahon, 1994) far outweighed possible side-effects. There are no trials that have specifically examined the role of lowering blood pressure in hypertensive subjects with CHD and therefore the results from the studies of hypertension in health individuals have been extrapolated to guide practice for the management of hypertension in patients with CHD. The results may underestimate the benefits of lowering blood pressure in hypertensive patients with CHD.

2.11.7 Lipids

The evidence from a large range of cross-sectional and longitudinal studies is consistent and indicates a direct association between plasma cholesterol levels and incidence of CHD (Isles, Hole, Hawthorne and Lever, 1992; Vartiainen et al, 1994; Shaper et al, 1985; Rose and Shipley, 1986). One of the earliest studies to show this relationship between populations was the epidemiological survey which became known as the 'Seven Countries Study' (Taylor et al, 1970). It demonstrated that the incidence of CHD was high in countries where median plasma cholesterol levels were high and correspondingly low in countries where median plasma cholesterol levels were low.

Evidence to support a causal relationship between plasma cholesterol and CHD mortality has been generated from major intervention trials. A review of 20 international trials testing diet or drugs or a combination of both, to lower blood

cholesterol have shown that there is a subsequent reduction in the risk of CHD. Furthermore, the CHD risk is dependent on both the extent of the reduction and on the length of time it has been sustained (Peto, Yusuf and Collins, 1985). When the results of these trials of cholesterol lowering were pooled, a 10% reduction in plasma cholesterol was shown to be associated with a 20-30% reduction in CHD (Yusuf, 1988; Peto.et al, 1985). However, these older trials were unable to demonstrate a reduction in total mortality and as a result the benefits of cholesterol lowering treatments have led to controversy in relation to supporting such treatments (Davey-Smith, Shipley and Rose, 1993).

Recently much more powerful lipid lowering medications that are able to reduce plasma cholesterol level by 20-25% (Levine, 1995) have been tested in randomised controlled trials. The results have been positive with statistically significant reductions in cardiac and all cause mortality in patients with CHD (Scandinavian Simvastatin Survival Study Group, 1994) and in primary prevention (Shepherd, Cobbe, Ford, Isles, Lorimer et al, 1995). In the former study, 4,444 males and females (19%) with a history of angina or myocardial infarction were randomised to active lipid lowering therapy (Simvastatin) or placebo. After a median of 5.4 years of follow-up, individuals in the active treatment group had a mean reduction in total cholesterol of 25% which was associated with a risk reduction in total mortality of 30%, $p=0.003$, and in CHD mortality of 42%, $p<0.001$ and revascularisation procedures of 37%, $p<0.001$. This work represented a landmark in the understanding of the benefits of lowering plasma cholesterol levels in individuals with CHD. It demonstrated for the first time that reduction in death from any cause could be achieved through lowering plasma cholesterol in individuals with CHD and moderately elevated cholesterol levels.

2.11.8 Lipids and CABG surgery

In the Postoperative Vein Graft Study (Lawrie, Morris and Earle, 1991) graft patency rates were assessed by angiography at intervals over a 20 year follow-up period. The influence of peri-operative and intra-operative variables on patency rates and overall survival were evaluated. Plasma triglyceride and cholesterol levels were not shown to influence survival rates but patients with elevated cholesterol levels had

significantly lower graft patency in the 10-20 year follow-up period. The presence of diabetes mellitus and elevated systolic blood pressure was associated with reduced survival rates. An excess mortality rate of about 20% was observed when the cohort was compared to a sample of the general population matched for age and sex. Cardiac deaths accounted for approximately 50% of deaths while approximately 25% of deaths were of unknown cause.

In an angiographic follow-up study of 188 men post-CABG surgery (on average four years previously), participants were randomised to either lipid drug lowering therapy (colestipol and niacin) or placebo (Blankenhorn, Nessim, Johnson, Sanmarco, Azen and Cashin-Hemphill, 1987). The direct effect of atherosclerotic plaque changes was assessed by angiography at baseline and again two years later. The total cholesterol level at baseline ranged from 4.8 to 9.1 mmol/L. In the treatment group there was a mean reduction in total cholesterol of 26%. The treatment group showed regression of plaque in both native and graft vessels in 16.2% of subjects compared to 2.4% in the control group and progression in 39% compared to 61%. The study concluded that direct benefits to limiting the atherosclerotic process could be achieved through lowering plasma total cholesterol levels for patients who had established CHD.

In another study using angiography assessment to document progression of atherosclerosis seven years post-CABG surgery, 284 patients who had at least one saphenous graft and pre-operative levels of cholesterol >5.5mmol/L had repeat angiographic graft assessment (Daida, Yokoi, Miyano, Mokuno, Satoh et al, 1995). Saphenous vein obstruction (narrowed by at least 70%) rates were compared among three groups (I, II, III) classified according to serum cholesterol levels measured at follow-up (I< 5.2mmol/L, II 5.2 -6.5mmol/l and III >6.5mmol/l). The number of grafts not obstructed were compared and were respectively 88% (I) vs 61% (II) v 57% (III), demonstrating that lower cholesterol levels were associated with a statistically significant lower rate of vein obstruction, $p<0.005$. Although this was not a large study, it provided evidence of the influence of elevated plasma cholesterol levels directly to the atherosclerotic process.

2.11.9 Diabetes mellitus

Both insulin dependent diabetes mellitus (IDDM) and non-insulin dependent diabetes mellitus (NIDDM) are associated with markedly increased risk of CHD, peripheral vascular disease and cerebrovascular disease (Pyorala, Laakso and Uusitupa, 1987). Diabetes mellitus has been shown to be a particularly strong cardiovascular risk factor in women that diminishes the relative protection against atherosclerotic disease observed in females without diabetes mellitus (Manson, Colditz and Stamfer, 1991). In addition, the attributable risk of diabetes mellitus for CHD is higher in women than men (Barrett-Connor and Wingard, 1983; Kannel and McGee, 1979). The excess operative mortality following CABG surgery in women has been related to presence of diabetes mellitus (Barbir et al, 1994; Carey, Cukingnan and Singer, 1995). In a Norwegian study of 912 men and 113 women followed for a period of over 7 years after CABG surgery, the relationship to both early and late outcome was examined in relation to the presence of diabetes mellitus (Risum et al, 1996). The prevalence of diabetes mellitus was 4.4% and no difference in early mortality was noted. In addition, there was no increased risk of major cardiac events in the diabetic population. Late mortality was increased in the diabetic population (relative risk 1.87, CI 1.60-2.14).

2.11.10 Obesity

Obesity has been described as one of the most important avoidable risk factors for a number of life threatening diseases and for serious morbidity (Garrow, 1992). The Department of Health statistics report that the prevalence of serious obesity has doubled in Britain between the years 1980 and 1991 with the trend continuing to increase (Bennett, Todd, Flatley, Freeth and Bolling, 1995). Degrees of obesity can be graded and a common classification has been described by Garrow (1992). Three levels of obesity are defined: that of, mild (BMI 25-29.9), moderate (BMI 30-40) and severe (BMI > 40).

The association between BMI and the three major cardiovascular risk factors of smoking, serum cholesterol and blood pressure were examined at a baseline assessment in a total of 16,113 people aged 30 to 59 years between the year 1972 and 1977. During a 15 year prospective follow-up study, mortality from CHD was

shown to be positively and independently associated with BMI for both men and women. The BMI associated risk was 1.03 ($p=0.027$) after adjusting for age, study year and all three CHD risk factors (Jousilatiti, Tuomilehto, Vartianinen, Pekkanen and Puska, 1996). Additional evidence for obesity as an independent CHD risk factor has been provided from the Nurses Health Study, a US cohort study which is following more than 120,000 women (Manson et al, 1995). The study demonstrated a progressive increase in CHD event rates with increasing BMI. The risk of death was 60-70% higher among women with a BMI of 29 to 32 than it was among women with a BMI of 25 to 27. In a UK survey of CHD risk factors in individuals with known CHD, a subgroup of 266 men and 259 women had undergone CABG surgery (ASPIRE Steering Group, 1996). At six month review post-surgery, 73% of men and 69% of women had a BMI of greater than 25.

In order to determine the effect of obesity on the results of CABG bypass surgery, a group of 250 obese patients undergoing surgery were compared with 250 age and gender matched controls of normal BMI (Prasad, Walker, Sang, Campanella and Cameron, 1991). Obesity was defined as a weight excess of 20% of the ideal weight (Broca scale). The obese group had a greater incidence of diabetes ($p<0.02$), hypertension ($p<0.05$), hyperlipidaemia ($p<0.05$) and left main stem coronary artery disease ($p<0.001$). The surgical procedure performed was the same in both groups although the time taken was longer in the obese group. Operative mortality was similar in both groups at 0.8%. On multivariate analysis, obesity was shown to be an independent risk factor for peri-operative morbidity ($p<0.05$). Significantly higher postoperative events included myocardial infarction ($p<0.02$), arrhythmia ($p<0.02$), respiratory infection ($p<0.001$) and wound dehiscence ($p<0.02$). At a mean follow-up time of 36.9 months, obese patients exhibited a greater incidence of significant recurrent angina ($p<0.01$) which was associated with a further average weight gain of 12.2 kg ($p<0.001$). Although the authors concluded that CABG surgery operative mortality was not increased in obese patients, aggressive pre- and post-operative weight control was indicated to reduce both peri-operative morbidity and the incidence of recurrence of angina.

2.11.11 Waist circumference

Waist circumference reflects total and abdominal fat accumulation and has been shown to relate strongly to health risk including the risk of CHD (Han and van Leer, 1995; Lean, Hans and Morrison, 1995). In a cross-sectional study, a range of health outcomes were investigated according to waist circumference in 5887 men and 7018 women aged 20-59 years from the general population in the Netherlands (Lean, Hans and Seidell, 1998). Waist was assessed in terms of action levels which were defined for both genders as: men (women): less than action level 1, <94.0 (80.0) cm, action levels 1-2, 94.0-101.9 (80.0-87.9) cm and more than action level 2 ≥ 102.0 (88.0) cm. The group with waist measurement less than action level 1 was used as the comparative reference group. A 4.5 fold increase (95% CI, 2.5-3.7) in risk of non-insulin dependent diabetes mellitus was documented in men above waist action level 2 and 3.8 fold increase (95% CI, 1.9-7.3) in risk for women; a 4.2 fold increase (3.6-5.0) and 2.8 fold increase (2.4-3.2) respectively in the risk of at least one major cardiovascular risk factor. The impact of increased waist circumference on outcome following CABG surgery has not been not been reported in the literature.

2.12 Patient perspectives on outcome following CABG surgery

2.12.1 Introduction

The literature that has examined patient views on benefits of surgery was not extensive. Two areas that focussed on this area of outcome were related to patient expectations in terms of functional recovery and in a related area pertaining to returning to employment. The latter has not been considered to be a useful index of outcome assessment given the many variables that influence an individual's ability to gain employment, none more than the lack of opportunities that exist in many areas of the United Kingdom.

2.12.2 Patients' expectations from healthcare treatments

Patients' views have become an important element in the evaluation of health care. A study was conducted to investigate cardiac patient expectations and satisfaction with health care following admission to hospital for investigation or treatment (Staniszewska and Ahemed, 1998). A total of 300 questionnaires were completed and analysis showed that expectations were a varying phenomenon, ranging in

content, strength and whether patients attached value to them. The study also reported that patients took their expectations into account when they evaluated care.

In a study interviewing 150 patients after they had undergone angioplasty the perceived complication rate and gain in life expectancy were documented (Kee, McDonald and Gaffney, 1997). Although most subjects had asked the Consultant questions prior to surgery, 70% (n=104) thought that the responses provided had not contributed to their treatment decision. The majority of subjects (75%) recalled a discussion of the complication rate of the procedure, but only 27% accurately estimated this rate, with 80% subjects overall believing that their mortality risk would be substantially or greatly reduced through having the procedure. The authors highlight the problem of ensuring that individuals can give informed consent properly when the risks and benefits of various treatment options have not been assimilated. The patients anticipated a gain in life expectancy of some 10 years but this was significantly in excess of the potential gain in life expectancy compared with their estimates of dietary control to lower blood cholesterol, not smoking and taking more exercise might produce (median 5 years respectively; $p<0.001$). The study concluded that patients greatly over-rate the capacity of angioplasty to control their disease with the procedure being viewed as more effective than risk factor modification.

The impact of expectations of outcome was the subject of a study examining quality of life and perceptions of the consequences of CABG surgery with 155 individuals interviewed approximately one year after surgery (King, Porter, Norson, 1992). Those subjects (n=64) who believed surgery was worth it because of functional improvement had more positive scores on subjective indicators of life satisfaction and mood than those believing surgery was worth it because it saved them from death (n=62), or those who were not sure surgery had been worth the effort (n=23). Differences in quality of life estimations between the groups were related to the focus of attention of those individuals. Individuals who perceived that they had gained improved functional status were described as being more likely to focus on a concrete outcome following surgery, whereas those who interpreted surgery in light of an

alternative to death were more likely to focus their attention on more effective aspects of recovery.

Other areas of health care intervention are similarly influenced by patient expectations. For example, in a study following 348 patients who had surgery for benign prostatic hyperplasia the effect of positive expectation on evaluation of outcome assessment were tested (Flood, Lorence, Ding, McPherson and Black, 1993). Positive expectations did not strongly influence a patient's report of post-operative symptoms or their overall health. However, strong support for positive expectations increasing the likelihood of reporting that they felt better after surgery, even after controlling for symptom changes. The study concluded that positive expectations resulted in a more optimistic view of improvement in health after surgery rather than altering reports of outcomes or health.

In an article by Chalmers (1995), a case is put forward for the need for reliable information about the effects of different types of health care interventions as a basis for patients to make choices. The intrinsic problem highlighted was when patients were faced with inadequately evaluated health technologies, how could they best protect their interests when the information was not necessarily trustworthy. The language of 'risk' was described as varied and has been described in a variety of ways, such as negligible, minimal, remote, very small, small etc. (Calman, 1996). This was considered to lead to confusion. The need for a classification system to aid understanding of the concept of risk, as well as the size of the risk was suggested and that it should include concepts such as avoidability, justifiability and seriousness (Chief Medical Officer, 1995). Chalmers (1995) concluded that clearer information was required about the factors that influence patients' choice of treatment, and more evidence about the extent to which they wish to be involved in making choices at all. An exploration of the patients' perspective on health care treatment was recommended. It was suggested that the evidence derived from basic research may be incomplete, and that in order to complete the picture and make it more relevant, then the public themselves should become more involved in the planning and promoting of research.

It has been proposed that in future research relating to standards of patient information, that an assessment of the impact of patient expectancy on health care outcomes should be made (Kee, 1996). It is unclear, for instance, whether patients with positive but unrealistic expectations of their therapy, ultimately do better or worse compared to those with a more realistic view. However, the implications for patient education may be different.

2.12.3 The patients experience of CABG surgery

In a study designed to examine the relationship of pre-surgery goals and baseline variables as possible predictors of unrealised benefits from cardiac surgery in an elderly population, a subgroup (n=97) of the cohort were undergoing either first time CABG or repeat CABG surgery (Gortner, Jaeger, Harr and Miller, 1994). Angina was the main presenting symptom (86%) reported at baseline. Patients' expectations of benefits were elicited on the day before surgery. Subjects were asked to indicate which of the following treatment goals they expected namely; prolongation of life, improved quality of life, return to former activities, travel and recreation, freedom from pain and fatigue. In addition, patients were given the opportunity to state their own personal goals.

All patients reported high ratios of expected to realised benefit with perceived prolongation of life, improved quality of life, and return to former activities being realised with the greatest frequency. For the small numbers of subjects who did not achieve their anticipated benefits, more severe angina at baseline and a high NYHA functional class at six months were significant predictors of unrealised improvement in quality of life ($p=0.016$ and $p=0.036$ respectively). This finding underscores the impact of angina relief on quality of life. Presence of diabetes mellitus, limitations in walking at baseline, postoperative complications and a higher NYHA functional class at six months were significant predictors of inability to return to former activities ($p=0.01$, 0.02, 0.05 and 0.04 respectively). According to patients' angina self-report, 7.4% of the total sample were free from pain and fatigue at baseline assessment. Postoperative complications significantly increased in likelihood when freedom from pain and fatigue was not realised ($p=0.0075$). The study did not report on the patients' own goals for outcome following surgery.

In a small qualitative study using grounded theory, nine patients were interviewed to explore the recovery experience following CABG surgery (Keller, 1991). This work found that the major process that individuals engaged in was the process of seeking normality and involved three conceptual stages; surviving, restoring and being fixed. The findings from this study provide an insight into the immense expectations of the benefits of surgery and that were described in terms of outcomes closely related to a biomedical model of health.

An insight into the problems experienced during early recovery following a cardiac event has been provided in a study that interviewed patients following a cardiac event (Jaarsma, Kastermans, Dassen and Philipsen, 1995). Patients (n=82) who had either had a myocardial infarction or CABG surgery were interviewed approximately six months after the event. The purpose of the interview was two-fold. Firstly, to explore any problems experienced by the subjects during the recovery period and secondly, to enquire about topics which subjects thought that they would benefit from more information. The majority (98%) of subjects stated that they had experienced some difficulties. On analysis of the responses, the main issues raised were identified as dealing with emotional problems, coping with changes to their physical condition and the deleterious effects on health following the event. Topics identified where more information would have been helpful were related to the nature of the interventions that they had undergone the deleterious effects of the intervention and the convalescence and recovery process and knowledge of the disease

2.12.4 Employment Status

Return to work rates after PTCA, CABG and medical therapy in patients who were currently employed with CHD were compared both in terms of actual numbers returning and in a subgroup the interval from procedure to return (Mark, Lam, Jones, Pryor, Stack et al, 1994). Patients who had PTCA were able to return to work earlier than both the CABG and medical therapy groups. However, by one year there was no significant difference in the employment rates among the three groups. After adjustment for the more favourable characteristics of those selected for PTCA and medical therapy (less severe disease, better LV function, less functional impairment), the return to work rates at one year varied from 80%-84% of the population. This

result was similar to another study (Pocock, Henderson, Seed, Treasure and Hampton, 1996) that reported similar of return to work of 78% (n=216, age< 60 years) after two years with individuals with angina much less likely to be employed than those symptom free. Although both of the studies referred to above reflect employment patterns both in the United States and the United Kingdom, areas such as Glasgow in the West of Scotland have particularly high unemployment rates and this index was therefore less useful as a measure of success of the CABG surgery.

2.13 Scope for improvement in the management of CHD risk factors

A cross-sectional survey of a representative sample of patients, with a clinical history of CHD was conducted which included a review of hospital medical records and patient interview examination. The objectives were to assess the potential for improvement in secondary prevention of CHD interventions on a national basis (ASPIRE Steering Group, 1996). A stratified sample of 12 Specialist Cardiac Centres and 12 District General Hospitals were included. This resulted in the identification of a total of 2583 patients, aged less than or equal to 70 years, in each of four diagnostic categories: CABG, PTCA, acute myocardial infarction and acute myocardial ischaemia without evidence of infarction. The main outcome measures utilised were CHD risk factors recording and management in medical records, together with the prevalence of control of CHD risk factors at interview six months later. In the CABG sub-group of 266 males and 259 females, 10.5% were current smokers. Post-CABG surgery, approximately 31% of men and 19% of females had elevated diastolic blood pressures exceeding 90 mmHg and 77% of men and 86% of women in the survey had total cholesterol levels exceeding 5.0 mmol/L at least six months after the procedure. These results confirm findings that were obtained in an audit of CHD risk factors in patients undergoing CABG surgery in the cardiac centre where the study was conducted (Lindsay, Tait, Lorimer, Shepherd, Carter et al, 1995). Definitions for categorising blood pressure have been outlined by the British Hypertension Society (Sever, Beevers, Bulpitt, Lever, Ramsay, Reid et al, 1993) and are as follows: isolated systolic hypertension 160 mmHg or greater, borderline isolated systolic hypertension in the range 140-159 mmHg and normal systolic blood pressure below 140 mmHg. For diastolic blood pressure the categories are: severe

hypertension 115 mmHg or greater, moderate hypertension in the range 105-114 mmHg and mild hypertension 90-104 mmHg. Target levels for desirable blood pressure are set at 90 mmHg and below for diastolic blood pressure and 140 mmHg and below for systolic blood pressure (Sever et al, 1993). The British Hyperlipidaemia Association's guidelines (Betteridge, Dodcon, Durrington, Hughes, Laker et al, 1993) for patients with existing CHD intervention level for total plasma cholesterol level to be >5.2 mmol/L on optimal diet. In addition to smoking, the other main modifiable CHD risk factors of hypertension and hyperlipidaemia remain areas for improvement in patient management if long term benefits for health are to improve.

2.14 Health definition and conceptual framework

2.14.1 Introduction

In this section the concept of health is examined from a theoretical perspective and is considered both subjective and objective views and measures of health. The relationship between health and illness is explored in general and specifically as it relates to quality of life and in the context of CHD. For the purpose of this thesis, health has been considered from the following perspectives:- that of CHD symptomatology, CHD risk factors, multi-dimensional measures of health and psycho-socio-demographic determinants of health as illustrated in the figure 2.1.

2.14.2 Terminology: Health, Illness, Disease and Well-being

In the following sections, the concepts of health and illness, disease and well-being are described by a number of authors and for clarity, the perspectives that these different terms represent are summarised.

The 'diseased-based' view of ill health is based on the premise that poor health is a function of an abnormality and the term 'disease' therefore has been used in a limited and scientific manner (Field, 1976). Illness conversely, refers to a person's subjective experience of "ill heath" indicated by reported symptoms and subjective accounts, such as pain, distress or discomfort. Furthermore, objectively defined 'disease' does not bear a simple causal relationship with subjectively reported experience of illness. As MacIntyre (1986b) noted, screening studies of random

cross-sections of the population have shown that very few people are without some abnormalities that can be defined as 'disease', even though many of the affected individuals are unaware of the disorders. In a similar manner to the perspective of illness, the term 'well-being' can also be viewed as a subjective view of a health state.

In the Oxford Health Lifestyle Survey (Wright, Harwood and Coulter, 1992) of those reporting long term chronic illness, only 28% reported that their health was fair or poor on a scale of excellent, good, through to fair and poor. This highlights the complexities of assessing health where individuals are very well aware of the diseased state and yet rate their overall health as good which would suggest that there is a complex meaning that people attach to this term 'health'. Many studies support the view that health should be regarded as a multi-dimentional concept; that is not only the absence of disease, but a positive state of well-being and a reserve of overall health determined in large part by individual constitution (Herzlich, 1973; Pill and Stott, 1982; Blaxter, 1985). Although health is generally characterised as a positive entity, individuals also have the ability to define health as co-existing with serious or long-term illness (Blaxter, 1990). The paradox is clear in that individuals are perfectly capable of admitting to serious illness and yet claiming to be healthy and, on the other hand, there are those who report symptoms who have no discoverable pathology. There is a growing consensus that individuals have important knowledge of their own health state (Tuckett, 1985), and therefore this view of health should be carefully recorded and monitored. This, in turn, has fuelled the search for better subjective measures of health.

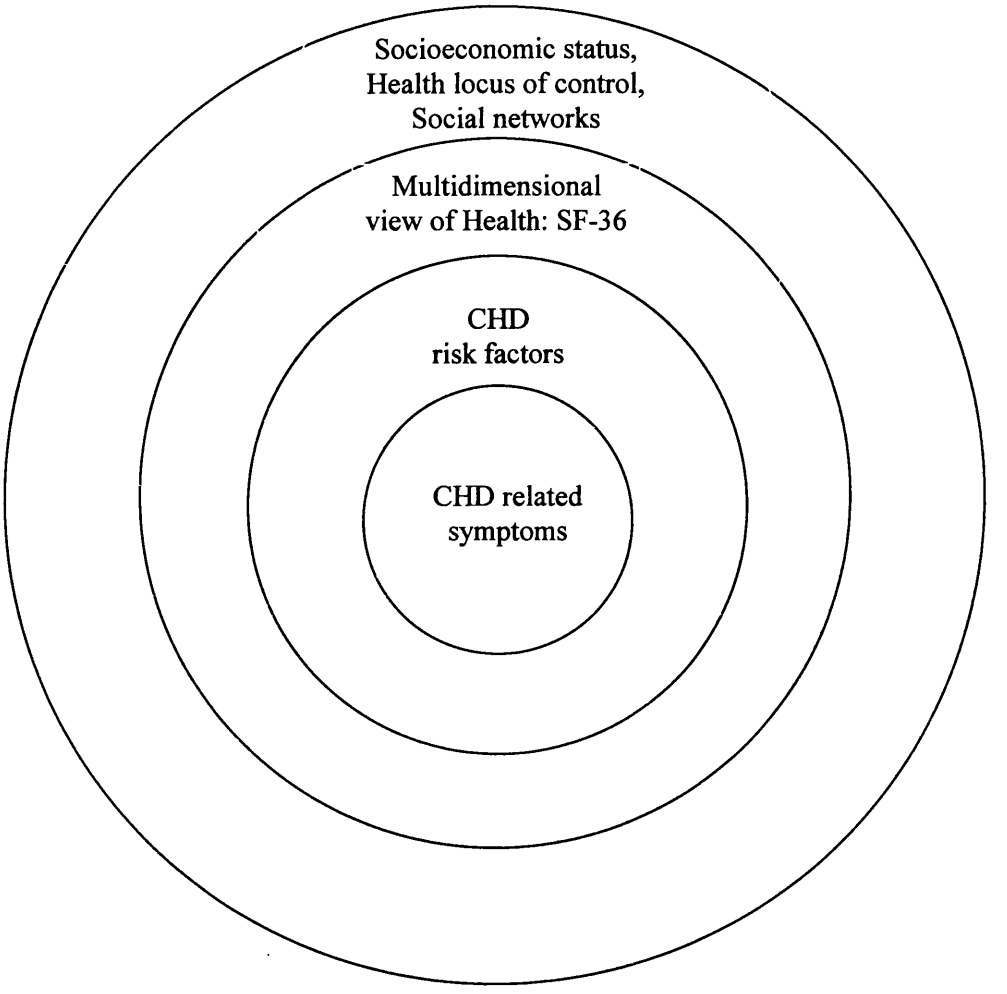

Figure 2-3. Schematic representation of health perspectives considered in subjects in study undergoing coronary artery bypass surgery.

2.14.3 Definition of health

The World Health Organisation (WHO) definition of health has embodied a multifaceted view of health with distinct components through which optimal levels of health can exist with or without the presence of disease. Health has been described as 'the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (World Health Organisation, 1977). This definition was widely endorsed but is now relatively dated and has been criticised for several reasons. It described 'health' as a 'state' which implied that it was a fixed and static entity and was viewed as a Utopian ideal with few direct applications to individuals or populations in practice. However, it was considered an advance at that

time because it introduced a multi-dimensional view of health and moved away from the disease model. One of its important concepts was related to the possibility of high levels of health in the presence of disease. More recently, WHO has explored a variety of newer definitions of health including 'a resource for living'.

2.14.4 Health within illness

Dunn (1973) defined health as 'an integrated method of functioning ... orientated towards maximising the potential of which the individual is capable'. Others have described health as 'the adaptive potential of the individual' (Dubos, 1965), 'harmony with self and environment' (Neuman, 1989) and conformity to social norms (Parsons, 1958). These viewpoints consider health status to include subjective dimensions that relate to the individual uniquely. Neuman (1989) proposed that health should be viewed as a continuum representing the degree of client wellness existing at any point in time. The energy level of wellness was considered to range from its maximum value at optimal health to value zero (total energy depletion) at death. This theoretical perspective of health could be considered to provide the basis for quantitative measurement of different levels of health.

Pender (1989) supported the need for a new approach to understanding health that combined both objective and subjective health perspectives. This approach excluded the possibility of physical and behavioural dimensions of health being viewed as separate or in opposition to experiential aspects of health. As a result, a unitary view of health was proposed (Newman, 1986; Neuman, 1989) where health is the positive state to be desired and illness or disease is the negative state to be avoided. Therefore a polarised view of health was generated where the positive state, identified with optimal health, was diametrically opposite to the negative state, identified with disease (Pender, 1989). The 'either or' dichotomy that was thereby created, precluded the existence of high levels of health in the presence of disability or disease and as such does not explain the complex and varied nature of health status in the context of disease or in its absence. There has not been general support for the latter polarised view of health. Moch (1989) proposed that there are many positive health states in the presence of illness. She justified this stance on the basis that the experience of illness has been credited with many rewarding attributes such

as 'stimulating personal transformation', a 'means of learning about oneself' and the 'opportunity to reflect on the meaningfulness of life' (Moos, 1982).

In a qualitative study, the experience of feeling healthy for people living with a chronic illness and/or disability was explored in a group of eight individuals using an interpretative phenomenological approach. The essential attributes that were identified by the participants were: honouring the self; seeking and connecting with others; creating opportunities; celebrating life; transcending the self; and acquiring a state of grace (Lindsey, 1996). These positive experiences were not documented by previous work that examined the impact of chronic illness. Factors such as sense loss of self-identity and strained and problematic relationships with others have been reported (Charmaz, 1997). A process of adaptation in order to cope has been identified by others and described as similar to grief (Matson, 1977). These differing perspectives of health within illness may be a result of the focus of the research question. The different accounts that were given could be explained by simply changing the emphasis of the area of enquiry from that of 'health' to that of 'illness'.

2.14.5 Health from a lay perspective

Medical knowledge rests upon the concept of disease whereas the lay perspective of health affected by illness has been described as being rooted in the experience of illness either personally or through others (Williams and Wood, 1986). Lay beliefs about illness are many and varied and do not simply mirror medical science. Although this may imply that they lack any scientific and valid basis, they have been shown to be logical, consistent and coherent, providing narrative reconstructions of the relationship between illness (Williams and Popay, 1996). Lay perspectives have been shown to bring together different aspects of the person's experience of the onset, course and effects of his/her illness in an attempt to make sense of this in causal terms (Blaxter, 1983). While the biological basis may be considered to shape and set limits on human experience, the recognition that 'it may tell us little about the social meaning and significance ascribed to such categories' has been cited as its major limitation in terms of understanding health (McIntyre, 1986).

Perceptions of health have been shown to change over the course of life although there are some common elements. These include the ability to function, energy and vitality, psychosocial well-being and the understanding and recognition that high levels of health can be present despite a major illness (Blaxter, 1990). The world of everyday life can therefore be viewed as the total sphere of an individual's experiences, being circumscribed by the objects of living and encompassing what is seen to be true or real to each individual.

2.14.6 Health related quality of life

A single comprehensive view of health has been considered widely to include a dimension of quality. Calman defined quality of life as 'the extent to which a person's hopes and ambitions are matched and fulfilled by experience' (Calman, 1984). Quality of life, as it has been traditionally viewed, embodies broader issues related to agencies and experience outside the domain of health (Farquhar, 1995; Meeberg, 1993). In addition to health, quality of life encompasses many other factors such as job satisfaction, family relations, standard of living, neighbourhood type etc. In order to overcome any confusion that may arise in the use of the term quality of life as it relates to health, health-related quality of life has been introduced to help focus on factors that are more directly attributed to health and health service activity.

In essence, the meaning of 'quality of life' still remains a matter of debate. There are no agreed definitions upon which to guide healthcare practice or research. Quality of life can be viewed from two broad conceptual bases. The first is that of a broad subjective interpretation of views and events (McDowell and Newell, 1987; Campbell, Converse and Rodgers, 1976; Bergner, 1985) and the second takes the view that quality of life can be reduced into functional component parts that can be used in health outcome measurement (Stewart and Ware, 1992; Jenkins, Jono, Stanton and Stroup-Benham, 1990; Aaronson, 1988).

In the literature such terms as health status, functional status, well-being and life satisfaction are sometimes used interchangeably with quality of life (Spitzer, 1987). There is general agreement that quality of life is a multidimensional concept (McDowell and Newell, 1987; Jenkins et al, 1990) that can be useful as a measure of

changes in health status as a result of healthcare interventions. Some authors believe that quality of life remains a fashionable idea rather than a rigorously defined concept in the health sciences (McDowell et al, 1987; Harrison, Juniper and Mitchell-Di Censo, 1996). Harrison et al (1996) described 'quality of life' in the context of assessment of health outcome as a person's 'conception of their health status and aspects of their life considered important in relation to their expectations of normal living'. This view encompasses the notions of a subjective evaluation of one's life against what is normal; an acknowledgement of expectations against natural capacity; and meeting personal goals by narrowing the gap between one's expectations and one's achievements. For the purposes of outcome measurement, the operational definitions are usually more restrictive and situation specific (Waltz, Strickland and Lenz, 1991). In the case of health related quality of life, the domains important to the study population and the health intervention under investigation are most commonly used as the focus for quality of life. Many available therapies offer similar morbidity and mortality outcomes, but different effects on quality of life, of which bypass surgery is cited as one such therapy.

The challenge for measuring effectiveness of interventions is to move beyond the traditionally cited statistics of morbidity and mortality end points (Jenkins et al, 1990). Evaluation of quality of life offers one approach to this challenge, taking the individual's subjective assessment into account (Oleson, 1990; Harrison et al, 1996) and recognising that these subjective patient perceived phenomena are valuable (Gill and Feinstein, 1994), although they can change within the same individual over time (Juniper, Guyatt, Willan and Griffith, 1994). However, there is an emerging consensus towards the acceptance of four broadly identified domains that are useful in the practical measurement of quality of life, namely: physical functional status, symptoms and side effects, social functioning and psychological state (Aaronson, 1988). The conceptualisation of quality of life ranges from a broad subjective basis to one that involves more objective specific functionary related criteria.

2.15 Health Outcome Measurement

2.15.1 Introduction

The measurement of health outcomes can be traced back to the works of Florence Nightingale (Nightingale, 1859). She described the three outcome measures of 'alive', 'dead' or 'relieved'. 'Relief' when interpreted as 'alleviation or deliverance from pain distress or anxiety', can be considered to contribute to 'quality of life', clearly demonstrating that this concept is not new. Patient outcomes form one part of a classic triad that have been used as a framework through which quality of care has been evaluated; namely, 'structure', 'process' and 'outcome' (Donabedian, 1980). Outcomes have been defined as the end result of medical care in terms of what happened to the patient and may be in terms of palliation, control of illness, cure or rehabilitation (Lohr, 1988).

The principal uses of outcome assessment have been summarised as;- provision of a description of the impact of care; generation of information for reliable clinical decision making and for the evaluation of the effectiveness of care under defined circumstances (Davies, Doyle, Lansky, Rutt, Orsolitis Stevic and Doyle, 1994). Outcome measures have been used to observe changes over time following a particular intervention and used to test causality in the relationship between the intervention and outcome.

The main reasons for establishing an outcome initiative have been summarised in a consensus statement (Davies et al, 1994) and include the following three areas:- to describe in quantitative terms the impact of care on patients' lives; to establish a reliable basis for clinical decision-making by clinicians and patients; and to evaluate the effectiveness of care and to identify opportunities for improvement. There may be many factors influencing a person's health, yet only some are related to the care received by that individual. If the outcome measures are used to judge performance, then there must be some relationship between the activities of the health care provision and the resultant patient or population outcome (Faust, Mirowski, Chuang, Lewis, Gonin et al, 1997). One of the key problems is the fact that there are many influences on health and that it may not be possible to identify realistic improvements in health that can be attributed specifically to a particular intervention. The

uncertainty of the links between the process and outcome of health care is a recurrent problem (Mullin, Baldwin and Perfetto, 1996) although there is agreement that an outcome measure should reflect the objectives of care.

In the Outcome Measures in Ambulatory Care Study (McColl, Steen, Meadows, Hutchinson, Eccles et al, 1995), criteria were identified that related to the practical issues of outcome assessment. The project team concluded that for outcome assessment to be a routine part of clinical practice, then the method had to satisfy some basic criteria, namely:-

- be inexpensive with simple methods of data collection;
- be unobtrusive to patient care;
- be able to generate clear feedback in a meaningful time frame;
- to have a relevant and appropriate scientific basis.

In terms of conducting a research study to evaluate the health outcome following an intervention as part of routine care, consideration of the above criteria should also be made in the design of the most appropriate outcome measure to be used.

2.15.2 Generic and Disease Specific Approaches to Health Assessment

There are two broad classifications of tools or measures designed to assess health status, that of disease-specific measure and generic measure (Donovan, Frankel and Eyles, 1993; Guyatt, Feeney and Patrick, 1993). A generic tool would be the preferred measure when comparing health levels in a general population, or in a variety of disease states. Generic instruments assess a spectrum of quality of life components or domains and are applicable to a variety of populations. They also allow for comparisons of health status across different disease states and patient groups (Oldridge, 1997). The disease-specific measures are useful in the context of one disease entity where health status may be affected by a range of symptoms related to a particular condition or disease. Specific instruments focus on problems associated with single disease states, patient groups or areas of function (Guyatt et al, 1993). Specific measures concentrate on particular conditions or populations. A growing number of researchers find it necessary to use, in addition to generic health status measures, disease specific measurements in order to capture the specific

quality of life issues associated with the condition of interest (Marks, Dunn and Woolcock, 1992; Juniper, Guyatt, Ferrie and Griffith, 1993). The generic health care measures can be criticised on the basis that they need to be broadly comprehensive in order to cover all conditions and diseases, but in so doing, they may fail to measure the specific and important impairments associated with any one condition. In addition, there is growing evidence that some generic measures may not be responsive to small, but important, changes when used to assess effective intervention (Anderson, Aaronson and Wilkin, 1993).

The strength of disease specific instruments lies in their ability to focus on the areas of function that have been considered most important to patients in relation to the symptoms and effects of the condition (McDowell et al, 1987). The limitation in using a disease specific measure is that the degree of impairment cannot be compared across different conditions. It is generally appreciated that individuals with and without disease have different health experiences. Smith (1981) supported the view that 'level of health', as a measurement, is most useful as a comparative entity rather than an absolute state in itself. In terms of health status measurement in practice, comparisons of health states between groups of individuals and of the same individuals before and after interventions are the most common usage of assessment.

2.16 The short form-36 general health status instrument

2.17 Introduction

The shortform–36 (SF-36) (Stewart and Ware, 1992) is a general health questionnaire that was developed in the United States and has now been adapted and used extensively in many countries. The SF-36 form is a single thirty-six item scale generating scores for eight health dimensions of health namely; physical functioning, role limitation due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health (psychological distress and psychological well-being).

2.17.1 SF-36 health assessment in patient groups

In a study to compare health status of patients with eleven common illnesses in Wales, the SF-36 questionnaire was applied during interview at a single time point in

1200 individuals (Lyons et al, 1994a). A response rate of 82% was attained and, on analysis of results, distinctive profiles were attained across the eleven disease states in the individual health domains within the instrument. The authors concluded that the SF-36 allowed comparison of the health status of patients suffering from different conditions. Responsiveness to change over time in the same groups is a prerequisite of a measure that is useful in the evaluation of healthcare outcomes.

The potential usefulness of the SF-36 for measuring different health states in a general population was investigated in the following study. Normative scores were calculated for two hypothesised large changes in health status namely; if health of individuals in social class V were improved to that of social class I, and secondly if the health status of men and women aged between 55 to 64 years was altered to the level of 45 to 55 year olds (Ziebland, 1995). There were small to moderate changes in the scores that underestimated the hypothesised change in health. The SF-36 scale may not be sufficiently sensitive when measuring different levels of health in a diverse general population group, but may be more useful for detecting changes in health status in groups that are more homogeneous in character. Normative scores for the SF-36 are provided in detail for US and UK populations in section 3.9.5.

The SF-36 health and well-being questionnaire has been used to assess changes in health status in a large population group, based on a longitudinal study with a mean follow-up period of 36 months (Hemingway, Stafford, Stansfeld, Shipley and Marmot, 1997). 5070 males and 2197 females aged between 39 to 69 years participated in the study. Health status was measured using the SF-36 and analysed in terms of its relationship to age, employment grade and disease status. Participants were categorised into four mutually exclusive groups according to their disease status at baseline. Healthy (free of the following conditions), physical disease only, minor psychiatric disorder only and both physical disease and minor psychiatric disorder. Physical diseases were defined as one or more of the following: angina (n=450), self report of doctor diagnosis of a heart attack or angina (n=150), possible ischaemia on resting ECG (n=707), hypertension or taking anti-hypertensive drugs (n=1554), claudication (n=125), diabetes (n=222), chronic bronchitis (n=914), musculo-skeletal disorders (self report n=1257) and cancer (n=128). Minor psychiatric disorder,

principally anxiety and depression, was defined as a score of greater than 5 on the 30 item general health questionnaire (n=1489). Changes in the SF-36 scale were examined by age, employment grade and disease status separately for men and women. A negative change reflected a decline in scores and, if valid, a deterioration in health. As expected, participants who had a high score at baseline had lower scores at follow-up and vice versa. Analysing such stages by using simple differences is problematic as the magnitude of the change would depend on the level at baseline. The SF-36 was shown to be a simple and inexpensive measure of health outcomes, able to detect changes in health in a general population. Each of the eight health domains of the measure showed a mean decline over the three years of follow-up. As hypothesised, employment grade was inversely related to decline, with lower grades experiencing greater deterioration than higher grades. The greatest declines were seen among subjects with disease at baseline, with the effects of physical and psychiatric morbidity being increased. Socio-economic status was inversely associated with both the risk of developing disease and the risk of people with disease experiencing complications. The disease groups were deliberately chosen to reflect morbidity that was chronic, progressive or recurrent.

2.17.2 SF-36 health assessment in patients with CHD

This lack of sensitivity of the SF-36 instrument with groups of individuals where only subtle differences in health status may exist was supported further in work undertaken to examine the impact on quality of life in two groups of patients with CHD. The patient groups were identified as Group 1 and 2. Group1: 45 patients before and after angioplasty; Group 2: 130 patients with stable angina). A generic scale (SF-36) and a disease specific tool Seattle Angina Questionnaire (SAQ) were employed (Spertus, Winder, Dewhurst, Deyo and Fihn, 1994). In the stable angina group, clinical changes were noted in the three month follow-up: some improved (n=18), some remained stable (n=79) and some deteriorated (n=33). Mean SAQ scores changed significantly and appropriately in each of these groups. By contrast, the SF-36 scales were unable to detect these small but clinically observable differences in condition in the angina group across all of its scales. However, the majority of the scales in both questionnaires improved significantly after angioplasty. The authors concluded that the generic health status measure SF-36 was useful in

evaluating marked changes in symptoms but was not as sensitive to the subtle changes in symptoms arising in the angina group as the disease specific measure. Other workers using the SF-36 to evaluate outcome following angioplasty in patients with CHD similarly found the scale to be useful in assessing outcome post-intervention (Krumholz, McHorney, Clark, Levesque, Baim et al, 1996).

A large study using the SF-36 questionnaire to evaluate the benefits of the addition of a nitro-glycerine patch to their usual treatment in 4,400 patients with stable angina over a six months period showed more positive results (Charlier, Dutrannois and Kaufman, 1997). The study objectives were to prospectively record the amount of anginal attacks, the need for rescue medication (sublingual nitrates) and SF-36 scores over a period of six months following the addition of a glycerine trinitrate transdermal patch in patients with stable angina. The design was open, non-comparative and prospective. The SF-36 scores ranged from 36.25 to 55.49 at baseline to 46.16 to 79.77 at six months. The scores were correlated with a statistically significant reduction in both frequency of angina attacks (3.38 per week vs 0.86 per week, $p<0.001$) and use of rescue medication (2.5 tablets/day vs 0.67 tablets/day, $p<0.001$). The authors acknowledge the potential of bias inherent in in open studies without a randomised control group together with a well established placebo effect on the introduction of new therapy in the management of angina pectoris which will likely favourable influence subjective assessments of health status. However, all eight domains of the health status profile clearly improved significantly during the study visit after visit and correlated with positive changes in clinical presentation.

The SF-36 instrument was therefore able to detect changes in health status with changes in clinical status for patients with stable angina pectoris. These seemingly conflicting results with the previously discussed study (Spertus et al, 1994) which found the SF-36 instrument to be insensitive to changes in health status in patients with angina pectoris may be the consequence of too small a sample size in the former study. This conclusion was supported by other workers (Weinberger, Oddone, Samsa and Landsman, 1996) who have shown than the SF-36 can be insensitive

when used over short intervals of time in small numbers of patients. They recommended using the SF-36 in studies with larger numbers.

2.17.3 Health status and quality of life in individuals with CHD

CHD affects different individuals in different ways. In some it may have no apparent affect. In others it may cause death preceded or not by symptoms and in a third group, it may cause incapacity due to angina. In the search for objectivity we often try to quantify the degree of incapacity due to angina with treadmill or bicycle exercise tests (Cowley, 1995). Even when these tests are continued to their maximum workload there is no indication that this correlates well with the incapacity experienced during daily life. More subjective assessments and accounts are necessary in order to improve understanding of the full impact of disease on an individual's lifestyle.

In a study comparing the symptoms and well-being following myocardial infarction in men and women in agreement with previous studies, female patients were older and sicker, they more often had angina, congestive heart failure and hypertension (Kitler, 1992). In terms of symptomatic differences these ranged from more pronounced symptomatic symptoms to psychological complaints, indicating that women had more difficulty in adapting after a heart attack. Another study examining at 5 years survivors of a heart attack showed that women has significantly poorer health related quality of life in terms of fatigue, sleep disturbances, emotional complaints, mobility, pain and social isolation (Wiklund, Herlitz and Hjalmarson, 1989).

Women are more likely to seek medical care when symptoms emerge (Verbrugge and Wingard, 1987) compared with men and also have higher overall rates of physical illness, disability days, physicians' visits and drug use (Verbrugge, 1989). Women claimed that their health status interfered to a greater extent with housework and social life than in men. This may be due to the fact that the responsibility for household and social chores in most families still relies almost entirely on the woman in the family. Nevertheless, after a heart attack, home and daily activity priorities tend to prevail. This may be one reason why women do not fear to utilise cardiac

rehabilitation programmes as often as men (Conn, Taylor and Abele, 1991; Hamilton, 1990).

The quality of life of people suffering from CHD was evaluated in a study that included 100 patients who had CABG surgery, 100 angioplasty and 80 medically treated patients (Lukkarinen and Hentinen, 1997). The NYHA classification, which is a measure of grades of functional status, was used as a quality of life assessment. Almost two-thirds of the patients (65%) were graded as having class three or four severity of symptoms, which meant that they had chest pain upon slight exercise or at rest. The health related quality of life across the six dimensions of health as measured by the Nottingham Health Profile (McEwen, 1988) was significantly poorer in a group of CHD patients than in an age and gender matched general population sample. The differences were most obvious on the dimensions of energy, pain, emotional reaction, sleep and physical exercise. Social isolation correlated with age, employment, financial status, mood, smoking and physical exercise. The authors concluded that CHD appears to handicap the person's entire life and to interfere with his/her basic daily activities, preventing physical mobility and sleep, causing a decline of energy, arousing the inevitable emotional reactions of fear and depression and resulting in an overall feeling of illness. The authors found that the Nottingham Health Profile was well suited to measuring the quality of life of CHD patients. It provided an accurate view of the sub-factors of quality of life in different patient groups, although it did not yield profound information on an individual's subjective quality of life.

2.18 Cardiac Rehabilitation and Secondary Prevention of CHD

Secondary prevention of CHD describes a range of interventions and preventive strategies to reduce the risk of further CHD events in individuals known to have CHD. It includes prophylactic medications, therapeutic and behavioural interventions to promote the adoption of a healthy lifestyle and reduce CHD risk factors. Changes in lifestyle can have a significant effect on the secondary prevention of CHD events following acute myocardial infarction (De Lorgeril, Renaud and Mamelle, 1994; Wilhelmsson, 1988; Burr, Fehily and Gilbert, 1989). Cardiac rehabilitation programmes are now widely available to patients after

myocardial infarction and following CABG surgery, and are the main area through which secondary prevention care is delivered. Cardiac rehabilitation (CR) has been defined by the World Health Organisation as the;

'Sum of activities required to influence favourably the underlying disease ..... the best possible physical, mental and social conditions....preserve or resume when lost as normal a place in the community..... must be integrated with the whole treatment of which it is only one facet' (World Health Organisation, 1993).

Exercise training remains the central and most common feature of CR programmes. Its origins can be traced back to the introduction of chair therapy as an alternative to prolonged bed rest (Levine and Lown, 1952) in the late 1940's. In its broadest context, CR should encompass risk stratification, quality of life and lifestyle modification as well as exercise conditioning (Pashkow, 1993). However, in practice CR programmes across the country vary considerably in terms of their individual combinations of exercise training, healthy lifestyle counselling, health education, spouse/partner support, stress management, their delivery setting (hospital-community- and home-based) and programme length (Thompson, 1994). Therefore the heterogeneity of the service provided and the outcome measures used in evaluation prevents large-scale evaluation of cardiac rehabilitation as a single entity.

Two large meta-analysis of CR have provided the strongest available evidence for its efficacy. Oldridge, Guyatt, Fischer and Rimm (1988) performed a meta-analysis of 10 randomised trials including a total of 4347 patients. CR was associated with a statistically significant reduction in all-cause mortality (24%, p=0.004)) and cardiac mortality (25%, p=0.006). Surprisingly, there were no significant differences in the rate of non-fatal MI between the intervention and control groups. This perhaps reflects the beneficial effects of CR in terms of reducing the severity of the MI. The second meta-analysis confirmed this latter finding. O'Conner, Buring, Yusuf, Goldhaber, Olmstead et al, 1989) a year later published a meta-analysis of 22 randomised controlled trials of CR including 4554 patients. All of the studies involved at least three years of follow-up after cardiac rehabilitation. At one year, sudden death was 37% less in the intervention group and the three year outcome showed a reduction in total mortality of 20% and cardiac mortality of 25% in the

intervention group compared to the control group, both results statistically significant. These meta-analysis were based on programmes that primarily involved exercise training and as a result could underestimate the benefits of a multiple intervention CR programme. Many of the individual trials on which these two meta-analyses were based were the same, and therefore the results of each analysis can be considered as providing confirmation rather than adding to the evidence of benefit of cardiac rehabilitation. Most of the participants were male (97%). A large range of time-points for recruitment to the intervention in relation to the myocardial infarction prevent extrapolation of the results to all patients and fail to give insight into when CR programmes should commence.

Small studies that have examined single aspects of CR such as psychological therapy and its effectiveness have been conducted using small sample groups, often in an observational study design. Despite quality of life improvement being a primary goal of CR, the evidence to support this achievement is disappointing (Pell, 1997). This may be related to the problems in both the definition and measurement of this aspect of health and well-being. Despite large numbers of eligible candidates, the specific number of individuals offered cardiac rehabilitation or who participate in CR programmes is not widely known. A study in the West of Scotland reported low uptake and completion rates of approximately 10% (Pell, Morrison, Blatchford, Pell and Dargie, 1996). In a review of CR services in England and Wales (Thompson, Bowman, Kitson, de Bono and Hopkins, 1997), wide variations in resources and focus of CR programmes were documented. Recommendations for the introduction of guidelines to provide both a framework and to determine minimum service provision for CR programmes were made.

2.19 Socio-economic and Psycho-social factors in relation to health

2.19.1 Introduction

A range of indices relating to measures of socio-economic status, social support and health beliefs have been described in the literature in the context of their relationship to health and well-being. This section reviews three areas; that of socio-economic deprivation, social support networks and health locus of control and examines their roles in determining health and illness experiences.

2.19.2 Socio-economic deprivation

The sensitivity of socio-economic circumstances to health is highlighted by the existence of large differences in health and disease experience across socio-economic groups. The relationship between increased risk of ill-health and disease with lower socio-economic status has been recognised for hundreds of years (Smith, Carroll, Rankin and Rowan, 1995). Depending on the classification used, two-fold, three-fold and four-fold differences in mortality have been reported in the United Kingdom (Goldblatt, 1990; Morris and Carstairs, 1991; Davey-Smith, Shipley and Rose, 1990). Socio-economic-related gradients in health have been explained in terms of their association with both social position and with different material circumstances such as bad housing, poor diets, inadequate heating, unemployment and poverty (Wilkinson, 1997). Furthermore, psychosocial effects of adverse social position have been implicated in the generation of health inequalities through an increased exposure to risk of chronic mental and emotional stress together with the related coping strategies of cigarette smoking and alcohol excess. These associations were also outlined in the Black Report (Townsend, Davidson and Whitehead, 1990), initially published in the early 1980's, now considered synonymous with the relationship between socio-economic deprivation and ill-health. It was concluded that smoking, diet and other behavioural factors interact with biological effects to contribute to, but not fully explain health inequalities.

An individual's biological development takes place within a social context which structures their life chances so that advantages and disadvantages tend to cluster cross-sectionally and accumulate longitudinally (Bartley, Blane and Montgomery, 1997). Examples of these relationships have been documented in many areas of achievement and in health status. In particular, children of less affluent families are more likely to fail at school (Essen and Wedge, 1992), to find work in the more disadvantaged areas of the workplace and to experience unemployment earlier in their working lives (Ashton, McGuire and Spilsbury, 1987). In addition, less affluent families are more likely to give birth to babies of lower birth weight, a factor which has been linked to socio-economic disadvantage in childhood and adolescence (Bartley, Power, Blane, Davey-Smith and Shipley, 1994). Other studies of low birth weight have linked this early disadvantage to an increased incidence of

cardiovascular risk factors (Blane, Hart, Davey-Smith, Gillis, Hole et al, 1996) and an increased risk of chronic disease in middle age; an effect that has been attributed to early biological programming of important homeostatic physiological functions (Barker, 1992).

The effect of socio-economic group on the incidence of, management of and survival after myocardial infarction and coronary death was analysed using a community coronary event register (Morrison, Woodward, Leslie and Tunstall-Pedoe, 1997). CHD events increased with age for both genders and were greater in men than women at all ages. The event rate increased 1.7 fold in men and 2.4 fold in women from the least to the most deprived socio-economic group (as defined by lowest quartile) (Carstairs and Morris, 1991). The proportion of individuals treated in hospital (66%) decreased with age, was greater in women than men and decreased in both sexes with increasing deprivation category. The study concluded that higher socio-economic deprivation group increased an individuals likelihood of a CHD event but decreased the chance of hospital admission. The likelihood of death following acute myocardial infarction was higher in individuals from lower socio-economic groups.

Carstairs and Morris deprivation scores (Carstairs and Morris, 1991) have been developed as a measure of socio-economic deprivation based on postcode of geographical area of residence. An updated version using 1991 census data has been used in this study (McLoone, 1994). Use of postcode has been reported to be more accurate than occupational classification when discriminating between socio-economically deprived groups because of high unemployment rates in sectors of the community (Tunstall-Pedoe et al., 1996). This information was routinely available on both death certificates and hospital discharge data. It has been criticised because it does not relate to characteristics of the individual or personal circumstances but to geographical area. However, postcodes have been shown to be useful in describing variation over a wide range of mortality, morbidity and other health related population measurements (Woodward, 1996; Watt, 1993; Carstairs and Morris, 1991).

2.20 Health Locus of control

Health locus of control beliefs have been described as the extent to which an individual uses internal or external attributions to explain events and actions (Wallston, Wallston, Kaplan and Maides, 1976).

The Health Locus of Control (HLOC) Model (Wallston et al, 1976) has been developed to measure the extent to which individuals believe that their health is influences either by their own behaviour or by external forces such as luck, chance or other powerful forces beyond their control. The concept has been derived from social learning theory (Rotter, 1954) according to which behaviour is a function of expectancy beliefs and the value that is placed on certain outcomes. Future behaviours, in a broad range of activities, are considered to be determined by socialisation experiences. Internal locus of control beliefs have been related in a positive way to health practices and general well-being with the converse true for external locus of control. These relationships have not been confirmed universally in studies that have assessed and evaluated measures of locus of control and health behaviour intentions (Wallston et al, 1976). The HLOC construct has been applied in a wide range of behaviours. Some studies have documented a positive relationship between internal HLOC beliefs and indices of preventative health practices (Duffy, 1988; Weiss and Larsen 1990).

In a follow-up study of 110 patients with established CHD and who had been admitted to hospital with exacerbation of symptoms, locus of control assessment and mastery of stress estimations were made using validated self-complete questionnaires (Younger et al, 1995). Mastery of stress has been described as a process through which stressful or difficult situations are overcome through the development of new capabilities, changing the environment and/or re-organising the self to re-establish meaning and purpose to life (Younger, 1991). Approximately 25% of the sample participated in the outpatient cardiac rehabilitation programme. Results showed that there were no differences in estimates of locus of control or mastery skills between attendees and non-attendees. However, internal HLOC was significantly and positively associated with a higher mastery score and with positive changes in health behaviours. These findings add support to the hypothesis that health-internals make

more attempts to control their environment and lifestyle. By contrast, other studies have failed to establish such a relationship (Norman, Redfern, Tomalin and Oliver, 1995; Steptoe, Wardle, Vinck, Tuomisto and Holte et al, 1994). In conclusion, HLOC remains of debatable use in terms of predicting behaviour changes and in the evaluation of determinants of health care outcomes. However, developments to incorporate HLOC assessment into a more general theory of health behaviour are being investigated in which the three concepts of the health value, self-efficacy and locus of control are combined (Wallston, 1992). The theory suggests that self-efficacy predicts health behaviour when the individual values their health and has an internal health locus of control. This interpretation remains to be tested although the author believes that self-efficacy is one of the most powerful predictors of health behaviour because it outlines a role for health locus of control as a more peripheral predictor of health behaviour, and has potential for improving the understanding of health behaviour.

Interpretation of the impact of health locus of control to health behaviour is made more difficult because of the confounding effect of social class since beliefs about illness have been linked also to socio-economic class (Pill and Stott, 1982). In their study that examined factors that individuals thought were causative agents for ill-health, home-owners were more likely to view a variety of diseases, such as heart disease and cancer to be caused in part by aspects of individual behaviour including diet, mental attitude to work and lifestyle habits compared to those who rented their homes from the local authority (Pill and Stott, 1982). The authors interpreted home-ownership as part of a cluster of social attitudes that emphasised the individual's control over life as opposed to notions of fatalism. The authors concluded that specific social and material conditions within socio-economic categories need to be considered in order to understand attitudes to health.

More than 10 years later, a large survey of approximately 1026 men and 1,700 women aged between 20 and 45 years, examining factors related to preventive health behaviour confirmed a strong relationship with social class (Pill, Peters and Robling, 1995). This relationship existed in men and women. The particular factors related to

social class were identified as education, tenure, residential overcrowding index and salience of lifestyle.

In conclusion, health locus of control has been shown to be a predictor of preventive health behaviour in some studies, although there is not unanimous agreement with this relationship. Preventive health behaviour has also been strongly linked to social class status and therefore an examination of the relationship between health locus of control and health practices should take into account the possible confounding effects of social class.

2.21 Social Support

Social support has been defined in the literature as the 'assistance and protection given to others', especially by individuals to individuals (Shumaker and Bronwell, 1984) and 'shielding people from the adverse effects of life stresses' (Cobb, 1976). Several conceptual definitions have been proposed and many different measurement instruments have been developed (O'Reilly, 1988). The form that support and protection may take can range from specific objective interventions such as financial aid to less tangible acts of caring and emotional support achieved through the sharing of issues and concerns. The main sources of social support have been shown to be associated with the availability of a spouse or confident, close ties with friends and the nearness of relatives (Brandt and Weinert, 1981). The key areas through which social support has positive health benefits has been related to its ability to enhance personal competence, health maintenance behaviours, especially coping behaviours, perceived control, positive affect, sense of stability, recognition of self-worth, decreased anxiety and depression and psychological well-being (Langford, 1997).

Many positive consequences of social support have been described with several large epidemiological studies documenting extension to life in people who are socially integrated (House, Landis and Umberson, 1988; Berkman, 1995). Increased risk of total mortality has been reported in socially isolated individuals (Orth-Gomer and Johnson, 1987; Kaplan, Solonen, Cohen, Brand, Syme et al, 1988). In a four year prospective study of adult males aged 42-77 years old, social networks were assessed at baseline and correlated with total mortality, incidence of cardiovascular disease

and stroke (Kawachi, Colditz, Ascherio, Rimm, Giovannucci et al, 1996). Socially isolated men were at increased risk of cardiovascular mortality (age adjusted relative risk 1.09; 95% CI 1.07, 3.37) compared to men with the highest level of social networks.

In a study examining the role of social support and long term recovery after CABG surgery, different aspects of social support were examined (King, Reis, Porter and Norsen (1993). The five areas of social support that were included were:- support in appraisal, self esteem, sense of belonging, closeness and tangible sense of social support. Utilising an Interpersonal Support Evaluation List (Cohen and Hoberman, 1983), to measure social support, the study demonstrated that the perceived availability of social support was related to outcome for patients and their spouses up to 1 year following CABG surgery. The results indicated that there was a differential influence in the five types of social support examined, and that perception of the availability of esteem support was the only type of support that consistently accounted for the unique share of the relationship between social support and outcomes. Esteem support was associated more strongly with positive emotional outcome and this may be because it is most closely associated with close relationships and is received at minimal social cost.

In summary, the literature acknowledges the difficulties in measuring social support although, using a variety of assessment approaches, it has clearly demonstrated a positive relationship between high levels of social support and improved health status.

2.22 Conclusions

The literature review has examined the epidemiology of CHD and the trends in incidence over the past ten years. It remains a leading cause of death and disability in society today. The underlying pathophysiology and clinical consequences have been reviewed and it is from this background that subjects will be selected for this study. The likelihood of developing this disease has been described in terms of CHD risk factors with the evidence to support this relationship examined in detail in general population groups and in individual groups with established CHD.

CABG surgery is one of several therapeutic options in the management of patients with established CHD. The development of this procedure has been reviewed from a historical perspective with an overview of outcome studies, based on mortality and morbidity statistics, presented. Atherosclerosis, the underlying disease process, has been shown to continue in grafted vessels. A large body of scientific evidence has been accumulated on the impact of established CHD risk factors on outcome following CABG surgery. The presence of the main CHD risk factors and their correlation with changes in health outcome will also be assessed in the subjects within the study. Cardiac rehabilitation programmes are a means through which individuals with CHD are helped and supported to optimal health states and the evidence to support its role has been reviewed.

The literature review has examined health from a variety of perspectives. A diverse picture emerges. Multi-faceted views of health that included concepts such as optimal levels of health in the presence of illness and quality of life as an attribute of health have been reviewed. A consensus that high levels of health can exist in the presence of disease emerges from the many commentators. Quantitative measures of health have been used to describe the assessment of outcome from health care intervention. Specific tools that are used in the study have been described in terms of their reliability and efficacy in measuring differences in health states between individuals at the same time point and in the same individuals at different time points. In terms of health outcome measurement with its often arbitrary and narrow criteria, the complexity of defining and quantifying health therefore presents many difficulties. Health status of patients with CHD has been described in terms of severity of symptoms and presence of uncorrected CHD risk factors that have been shown to increase the likelihood of further coronary events. Major psycho-socio-economic indices that have been associated with different levels of health and disease states have been reviewed in general and in relation to CHD and CABG surgery. There is a large literature covering a range of factors in relation to their impact on CHD progression in general and for patients following CABG surgery. This work will examine the effect of such documented factors in this study group. In addition, the relationship between the variety of health perspectives assessed before and following CABG surgery will be examined. The objectives of the study were to

provide greater understanding of the health benefits of CABG surgery which include a patient perspective on outcome.

Chapter 3

3.1 Literature pertaining to the method

3.1.1 Introduction

In this section the theoretical basis of the research methods and data collection tools used within the study are reviewed. The conceptual basis and development of the individual instruments that have been selected to measure the health status, health locus of control and social network are described together with justification of their relevance to addressing the research questions.

3.2 Research Methods

The study was designed as a prospective descriptive study with two assessments, one at baseline and the other at approximately 16 months following CABG surgery (Polit and Hungler, 1997). The objective of the selection of this design of study was to provide greater understanding of the health and well-being and experience of patients undergoing CABG surgery through the systematic collection of a range of variables describing different dimensions of health. On the basis of the literature reviewed in relation to outcome following CABG surgery, little in-depth contemporary information was found on the health and well-being of patients before and after CABG surgery or the possible relationship between a range of patient variables.

A descriptive study makes no attempt to manipulate variables beyond summary and correlation statistics (Carter, 1996). The advantages of this design have been described as its breadth of scope, flexibility in areas that are amenable to enquiry and the ability to examine the relationship between variables over time (Oppenheim, 1992). An important factor in this design is to obtain a representative sample of the population group under study in order to maximise generalisability (Oppenheim, 1992). Within a descriptive study design different research methodologies can be utilised together with a range of data collection instruments and variables. Both quantitative and qualitative research methods were used in this study together with self-complete questionnaires, clinical assessments and structured interviews for data collection. These are discussed in more detail in the following sections

3.3 Quantitative methodology

Quantitative research methods have been influenced by the philosophical perspective of positivism that underpins the basic sciences, such as physics and chemistry. It has been described as a method of enquiry that relies on 'tested and systematic experience rather than undisciplined speculation' (Norbeck, 1982). Complex issues are simplified through a process of reduction into measurable units that can be observed and recorded. Quantitative methodology primarily focuses on the measurement and assessment of previously known identifiable variables. Subjects are viewed objectively in an attempt to identify and measure important characteristics (Polit and Hungler, 1997). The responses that are generated are either numerical or adapted to generate a numerical score. Data generated by this method can be analysed to identify trends and be subject to statistical testing. Quantitative methods have been employed in the evaluation of 'cause and effect' relationships in experimental studies and in the testing of theories through the collection of data to support or reject them (Parahoo, 1997). Correlations and regression statistical techniques (Altman, 1992) can be employed to assess the association between one or more variables for example weight loss and blood pressure. Correlation analysis is used to assess the degree of linear association between two continuous variables. Regression techniques are used to examine the extent to which one variable may be explained by a linear combination of one or more of the other variables.

An illustration of this technique can be seen in a study designed to examine the linear association of two quality of life measures that differed in the length of time required for completion. A statistically significant correlation was demonstrated and allowed the authors to justify using the shorter quality of life measure because the results correlated significantly with the longer 'gold standard' measure. A particular feature of that study and other quantitative research in nursing (Cheater, 1993) is the ability to analyse paired data sets. This eliminated the need to take account of between-subject variability and is therefore an important consideration in studies designed to evaluate outcome following an intervention or procedure.

In summary, quantitative research methods have been shown to have wide applicability to health service and biomedical research because of their ability to

measure differences within and between populations groups and in the assessment of an extensive range of characteristics and variables of importance to the health and well-being of individuals (Abrams and Scragg, 1996).

3.4 Qualitative methodology

The broad school of thought that underpins qualitative research methods is known as 'interpretivism' and is described as the belief that 'the social world is actively constructed by human beings' and that 'we are continually making sense of it' (Milburn, Fraser, Secker and Pavis, 1995). According to van Manen (1977), qualitative data with its emphasis on people's 'lived experience' are fundamentally well suited to capture the perceptions, assumptions, pre-judgements and presuppositions that individuals make in the context of the social world around them.

Within the area of qualitative research methods there are a diversity of approaches with different theoretical presuppositions. This study adopted a phenomenological approach, as described by the early 20th century German philosopher Husserl, and whose applicability to nursing research has been supported by Koch (1995). It focused on describing the manner in which an individual experiences a phenomenon and the way in which this is expressed. A phenomenon has been described as 'the abstract entity or concept under investigation in a study, most often used in place of the term variable' (Polit and Hungler, 1997). The notion that those who experience the phenomena, are uniquely placed to comment with authority to others, is implicit within the theoretical assumptions that underpin this method (Miles and Huberman, 1994). The role of the researcher has been described as identifying patterns or commonalties in the individual accounts provided by respondents from examination of specific instances or events (Miles and Huberman, 1994). During analysis, data are synthesised to generate abstract themes within the narrative data. The final stage involves the identification of concepts and theory (Morse and Field, 1996). The goal of qualitative research is to develop concepts that improve understanding of social phenomena in natural setting, giving due emphasis to the meanings, experiences, and views of all the participants (Pope and Mays, 1995). Qualitative research methods have been shown to be suited to understanding issues such as teenagers and young working class women being aware of the health education messages on smoking but

not perceiving them as relevant to their everyday life (Graham, 1993; Amos, Currie and Hunt, 1991).

3.5 Issues of reliability and validity in qualitative research

Five areas have been identified as possible threats to external reliability (Miles and Huberman, 1994); the researcher, informant choices, the social context in which the data are gathered, the definitions and delineation's of the construct, the methods of data gathering and analysis. Threats to external validity are those that obstruct or reduce a study's comparability.

The amount and quality of the data generated on the depth of the analysis are dependent upon the ability of the researcher. The interviewer must be able to establish rapport with the interviewees to gain trust. The depth of the data analysis depends upon the researcher's sensitivity, perceptions, informed valued judgements, insight and knowledge. The purpose of qualitative research is not to determine objectivity, i.e. what actually happened, but rather to report objectively the perceptions of each of the participants in the setting. Qualitative research that relies exclusively on observation by a single researcher has been criticised on the grounds that it is limited by definition to the perceptions and introspection of that individual (Miles and Huberman, 1994; Pope and Mays, 1995). In addition the researcher, as tool of data collection and analysis, selects and rejects data subjectively. Leininger (1994) argues that the major threat to credibility is too little time in the field to understand the lived-through experience of those studies. To ensure conformation of results,, the researcher must obtain evidence from informants on the researcher's findings or interpretations, returning to the informants to check the emerging theory (Leininger, 1994). She also recommends the use of audit trails and triangulation of data sources.

Internal validity addresses the problem of whether conceptual categories have shared meaning between the participants and the researcher. Theoretical verification can be achieved in two way. The first is verification of the findings with the participants of a research study and secondly, verification with the related literature and the researcher must identify related concepts found in similar settings.

Not all researchers agree on the need for high levels of rigour in qualitative research. Sandelowski (1993) makes the case that the criteria of reliability and validity are inappropriate, uncompromising, harsh and rigid. She argues that repeatability is not an essential property of qualitative interviews. She sees one of the major threats to constructing validity, that is the views of the informants, as the assumption that validity rests on reliability.

3.6 Triangulation of methods

Triangulation denotes a combination of research strategies brought together to achieve a multi-dimensional view of the phenomena of interest (Sandelowski, 1995). The aim of triangulation methodology is to choose sources that have different biases and different strengths so that they can complement each other. According to Mitchell (1986), the concept of triangulation originated as a navigational strategy wherein multi-reference points were taken to locate an unknown position. Each method implies a different line of action towards reality (Denzin, 1989) and hence reveals different aspects of it. Qualitative and quantitative research methodologies have individual method-specific theoretical assumptions that should remain intact within methodological triangulation (Foster, 1997). Most investigations can be seen as stressing one dominant method with combinations of the others as additional dimensions. The results generated by different methods should not be expected to fall into a coherent single answer and the strength of the process is that different pictures are allowed to emerge (Patton, 1980). This can result in simultaneous data collection in which one method is supplemented by the other with different weighting attached to each (Morse, 1991). In terms of interpretation of data sources when the results depict divergent views it has been recommended that researchers should make judgements about the relative roles of the data ahead of time (Chelsa, 1992; Morse, 1991).

The linking of both quantitative data generating numbers, and qualitative data generating words, in methodological triangulation has been advocated as a means of 'bringing our quest for understanding of the real world much closer' (Miles and Huberman, 1994). Salomon (1991) supported the adoption of multiple methodology because of its ability to capture a 'systemic' approach to understanding the

interaction of variables in a complex environment. This could be achieved through examination of areas where data confirm, conflict and complement each other. As a result, rich detail, clarification, and a greater insight of the area under study are generated, as well as, a mechanism through which theory can be strengthened and revised (Miles and Huberman, 1994).

A study conducted using methodological triangulation to examine the health of families used a combination of questionnaire survey and in depth interviews (Cornwell, 1984). The authors were able to provide a clear distinction between the public and private accounts provided by respondents highlighting often contradictory and complex beliefs that people held. The linking of these methodologies enabled through triangulation (Foster, 1997) allows the area under enquiry to be expanded and developed providing greater understanding of the health status and life experience of the subjects within this study.

3.7 Methods of Data Collection

3.7.1 Structured Interviewing

The structured interview is based on a schedule of pre-defined questions. The interview schedule serves to standardise the interview, with the same questions asked in the same order to minimise inter-interview differences that may influence the response of the subject and thus the results generated in the study. The benefit of the interview as opposed to a self-complete questionnaire is the opportunity to offer clarification and support if needed (Parahoo, 1997) and to optimise response rates to the questions. Structured interviews are recommended when the purpose of the study is to obtain the same information from all of the subjects, when comparisons are to be made across respondents and particularly when the setting or background to the study setting is relatively homogeneous (Waltz Jr, Snow, Kosinski and Gandek, 1991). Such attributes were important to the systematic collection of data that would allow the research questions within this study to be addressed.

3.7.2 Questionnaires

The use of the questionnaire is the most common method of data collection used in nursing and health services research (Polit and Hungler, 1997). Questionnaires are

also used in a wide range of everyday life situations to assimilate sets of information; for example to fulfil criteria for opening a bank account or as a market survey tool to gather opinions from a population sample on television programmes. As such people are familiar with the questionnaire as a means of collecting information. It has been defined as a 'series of questions for purpose of obtaining information' (Oppenheim, 1992). The questionnaire can be regarded as a research tool when it has been designed and administered for the purposes of collecting data, according to a research protocol in a rigorous and systematic manner with due attention given to the relevance of the questions to the research objectives (Polit and Hungler, 1997). A questionnaire may be self-administered or administered during interview by the researcher. The former approach has the advantage of being less time-consuming and can be utilised in studies involving a large number of subjects. However, response and completion rates have been shown to be lower than administration by a researcher. In order to be able to claim that the data collected by a questionnaire was representative of the whole study group, response rates require to be of the order of 50-60% or above (Burns and Grove, 1993).

The individual questions within the questionnaire were based on open and closed questions; questions based on the critical incident technique; rating scales and the validated questionnaire tools namely; the SF-36, Health Locus of Control and the Social Networks Scale which are discussed in the following sections.

3.7.3 Open and closed questions in the questionnaire

Closed questions have been recommended to be used when it is anticipated that the majority of the possible responses were already known (Henerson, Morris and Fitzgibbon et al, 1987) and to focus the responses. This can be a limitation as a relevant option may be overlooked. To address this, the option of 'other, please specify' can be included. This has been called a semi-closed question by some authors (Lydeard, 1991). When the respondents' views and beliefs were the subject of enquiry, an open-ended question style (Parahoo, 1997; Lydeard, 1991) can be used. This style of question provided an opportunity to collect information and identify areas of interest not anticipated in advance. Although Lydeard (1991) warns of the possible difficulties in interpretation and analysis when lengthy responses are

given which may be ambiguous and contain too many ideas and thoughts. The space for the respondent to answer the question gives some indication of the general length of the expected response. Because of these issues open-style are often more appropriate for use in an interview situation where clarification and further guidance can be offered.

Critical incident technique (Cormack, 1996) is a means of enquiry used to collect direct observations of an attribute or a service to aid understanding of its important strengths and weaknesses. This data collection technique was developed by Flanagan (Flanagan, 1954) an American psychologist working during the 1950s. It has been used increasingly in nursing medical research in the United Kingdom (Hulka, Kupper, Daly, Casel and Schoen, 1975). The method has been used to explore consumer views of care provided by Macmillan nurses (Cox, Bergen and Norman, 1993) and to elicit indicators of high and low quality nursing care from patients and their nurses on medical, surgical and elderly care wards (Norman, Redfern, Tomalin and Oliver, 1992).

3.7.4 Critical incident technique

An incident has been described as relating to any observable human activity that is either a complete entity or at least an entity with a limited number of key identifiable components to permit views and assessments to be made thereof. A behaviour or activity that has been perceived as making a significant contribution either positively or negatively to a specific task or objective has been defined as critical (Ronan and Latham, 1974). It can be viewed as a 'snapshot' of an activity that minimises generalisations and bias for the 'middle ground'. The technique relies on the respondent being able to distinguish between what was effective or ineffective within the area of inquiry. This can potentially be a problem with individuals who are passive in nature or who have not formulated any judgements of the incident under enquiry. However, the critical incident technique has been shown in other work of being capable of generating a comprehensive description of the meanings encompassed within quality of nursing as perceived by patients and nurses with their varying perspectives (Norman et al, 1992). Flanagan maintained that an incident may be considered valid if full details can be given of the incident and its context by the

respondent (Flanagan, 1954; Ronan and Latham, 1974). The advantages of framing an open question on the critical incident technique is that it increases the likelihood that subjects will respond with negative as well as positive incidents that they have observed. Thus the problem of a positive response set (Hulka et al, 1975) which has been identified frequently by researchers seeking to elicit patients' opinions of their care, is minimised

3.8 Rating Scales

3.8.1 Visual Analogue Scale

Visual analogue scales have been widely used in the measurement of psychological attributes (Kee and Kieckhefer, 1989) and have subsequently been applied to the problem of rating pain (Huskisson, 1974). The scales originated in early work which developed visual analogue scale to measure attitudes and beliefs (Likert, 1932), and often such scales are referred to as 'Likert scales'. The explanatory details for completion are brief and simple. Such scales have been found to be useful in clinical practice because they can be administered quickly and are suitable for measurement of subjective feelings, sensations and symptoms (Cline, Herman, Shaw and Morton, 1992; Waltz et al, 1991). In addition, the scale has been shown to be useful in charting changes over time in the particular attribute being assessed.

Reliability of the visual analogue scale in symptom assessment was confirmed in a study which examined the correlation of scores when repeated measurements of pain were assessed and also when comparing responses obtained using horizontal and vertical scales (Scott and Huskisson, 1979). A correlation coefficient of 0.99 was calculated between scores obtained in the repeated measurements, although scores on the horizontal scale were non-statistically significantly lower than on the vertical scale. Validity was tested through comparison of a visual analogue scale and a four-point descriptive scale rating pain as slight, moderate, severe, or agonising (Scott and Huskisson, 1976). A correlation of 0.75 was reported although the authors acknowledged that the relationship was likely to be attenuated by the restricted number of categories on the descriptive scale.

3.8.2 Semantic differential scale

The semantic differential scale was originally developed by Osgood, Suci and Tannenbaum (1957) and is another technique to measure attitude or feelings towards a concept or phenomena. The scale is anchored at both ends and based on the principles of both the visual analogue scale which generates a continuum of responses and the Likert scale which has categorical responses as discussed in section 3.8.1. Hennerson, Morris and Fitz-gibbon (1987) describe the scale as consisting of a series of adjectives listed on opposite sides of the page with seven attitude positions in between. Respondents were asked to put a mark in the space provided as quickly as possible to give their immediate reactions of their feelings pertaining to the entity being measured. Such scales are used with the assumption that the 'meanings often can or are usually communicated by adjectives describing degrees of feelings, symptoms or emotions'. The score obtained from each respondent is described as an indication of the strength of their attitudes or feelings and such scores can then be subjected to statistical analysis. The rating scale is a highly acceptable and frequently used measure of attitude and feeling, acknowledging that it only yields general impressions without information about the underlying reasons for their feelings or levels of symptoms. The semantic differential scale has been used to measure perceptions of stress (Rosenfield and Stevenson, 1988) and to evaluate the effectiveness of a health promotion programme in individuals with low and high depression scores in the assessment of symptoms severity, limitations and life quality (Braden, 1992). In both studies the rating scale proved useful in discriminating between different degrees of the attributes under study. Although this is an important feature of a measure, validity was not established through assessment of the responses with other measures of the attribute or symptom being assessed.

In the work undertaken in this thesis, the rating scale was based on a horizontal line anchored at each end by terms that represent the extremes of symptoms experienced as a result of angina pain and breathlessness, similar to that described in other studies evaluating pain symptoms (Scott and Huskisson, 1976; Huskisson, 1982). This rating scale was selected in order to have an instrument that was able to measure a range of responses that could be used to differentiate symptoms levels between subjects at one time point and in the same individual over time. The seven-point

scale provided a limited option for responses as opposed to the infinite number of responses possible using the visual analogue scale, which may have little clinical application and to provide a broader range of grading than the NYHA scoring system. The subjects were asked to score the level of symptoms at that moment in time rather than over a prolonged period of time. This single time point was selected because it was considered to most closely reflect the day to day evaluation that individuals make on the severity of their symptoms.

3.9 Short-Form-36 General Health Measure

3.9.1 Introduction

The Short-Form-36 (SF-36) is one of several health status questionnaires widely used in the United States by the Medical Outcomes Study (MOS) (Tarlov, Ware, Greenfield, Nelson, Perrin et al, 1989) and as the name suggests is a shortened version of a longer instrument. As a basis to the development of these instruments existing health measurement scales developed in the Rand Health Insurance Experiment (HIE) (Ware Jr, Brook, Davis and Lohr, 1981; Lohr, Brook, Kamberg, Goldberg, Leibowitz et al, 1986a) were used. The HIE was an evaluation by the Rand Corporation of different ways of funding health care and was undertaken between the years 1974 and 1982 in the United States. This work has provided an extensive application of psychometric theory and methods to the development and refinement of health status measurement in the general population. The process involved the use of standardised tests and scales to measure attributes of individual's ratings of health and translate these into scales that could be applied to the measurement of health. However, the efficacy of such a tool for use with an older population or in disease states was not examined. This became the primary objective of the MOS (Tarlov et al, 1989) together with further refinement work to improve efficiency, reliability and validity of the health status measures. The MOS was a large-scale cross-sectional study of variations in physician's style of care delivery and adult patient outcomes in different systems of care in the United States. Clinicians (n=523) and adult patients (n=22,462) were randomly sampled from different health care settings. A necessary prerequisite to the study was the development of health status measures that were comprehensive and psychometrically sound yet short enough to be practical for use in large scale studies of general populations and for use

at an individual level for patients in practice settings. It was also intended that the measures would be applicable in health policy research in the evaluation of the effects of health care and in clinical trials.

3.9.2 SF-20 Questionnaire

Several health status measures were designed for the MOS, namely the SF-20, the SF-36 and more recently the SF-12. The numbers refer to the number of questions in the instrument. The SF-20 was based on the original health insurance instruments and was one of the first shortened forms of the original battery of questions to be developed and tested as part of the medical outcome study (Ware, Sherbourne and Davies, 1992). Six health concepts are represented with between one and six items in each dimension. These are physical role and social functioning, mental health, current health perceptions and pain. The SF-20 has achieved levels of internal consistency on multi-item dimensions which are only marginally lower than those obtained from the corresponding full length measure and in all cases were shown to be acceptable for group comparisons. However, the SF-36 measure has been shown to out-perform the SF-20, achieving marginally lower scores than the parent measures for bodily pain and mental health, but matching them for physical health and role functioning and exceeding them for social function (McHorney, Ware Jr., Rogers, Raczek and Lu, 1992).

3.9.3 SF-12 Questionnaire

The most recently developed health instrument from the MOS is the SF-12 questionnaire (Ware, Kosinski and Keller, 1996). The rationale for its development was based on the fact that the SF-36 physical and mental health components were able to capture approximately 85% of the reliable variance in the eight scales SF-36 health profile. Therefore it was concluded that if two health dimensions, as a health outcome measure, were satisfactory for many purposes, a survey with fewer questionnaire items could be constructed to estimate these outcomes. Twelve SF-36 items have been used to design the questionnaire and have been shown to reproduce at least 90% of the variance in the individual mental health and physical health scores from the original SF-36 health domains. The SF-12 reproduces the eight-scale profile with fewer levels than the SF-36 scales and yields less precise scores as would

be expected for single-item and two-item scales. The authors claim that for large study groups these differences are not important because confidence intervals for group averages in health scores are largely determined by sample size. Preliminary tests of reliability and validity have been completed (Ware, Kosinski and Keller, 1996). Average scores for the two summary measures, and those of most scales of the eight-domain profile based on the 12-item short-form, closely mirrored those for the SF-36, although standard errors were nearly always larger for the SF-12. The authors concluded that the SF-12 health questionnaire is most likely to be a satisfactory alternative to the SF-36 when samples are large and the objective is to monitor overall physical and mental health outcomes.

3.9.4 SF-36 Purpose and Development

The MOS instruments were designed for two major settings - a general population survey and a four year longitudinal study of individuals with five medical conditions namely hypertension, congestive heart failure, recent acute myocardial infarction diabetes mellitus and severe depression. A comprehensive general health survey instrument consisting of 149 items, with 40 separate scores covering 35 domains referred to as a 'functioning and well-being' profile was developed. Subsequently, in an effort to reduce the burden of an extensive battery of questions, short-form versions of the 'functioning and well-being' profile were developed. The SF-36 has been based on definitions of health and components of health status from several sources including: the World Health Organisation (1977) definition that distinguishes between physical, mental and social well-being and the constructs developed for the MOS and the HIE surveys that were based on professionally defined multidimensional model of health.

3.9.5 SF-36 Scale Development

The SF-36 health measure was constructed to represent eight of what the authors considered to be the most important health concepts included in the MOS and other widely used health surveys. Both physical and mental health concepts with multiple assessments of functioning and well-being were included to ensure content validity in relation to accepted definitions of health (Ware Jr, 1987). Multiple categories of operational health definitions were selected to measure both physical and mental

health in terms of behavioural functioning; perceived well-being; social and role disability; personal perceptions of health in general. The resultant SF-36 form was a thirty-six item scale generating scores for eight health dimensions of health namely; physical functioning, role limitation due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health (psychological distress and psychological well-being). The scores for each domain are based on the same scale of 0 to 100 where 0 is the worst possible health status and 100 the optimum. The scales were scored using Likert's (1932) method of summated ratings that assumed the range of responses to items within the same item are equal. Each item was assumed to have a linear relationship with the score for its scale. The eight scales on the SF-36 have been shown to have high internal consistency (Cronbach Alpha 0.76-0.86) (Hemingway et al, 1997). Content validity (the extent to which SF-36 comprehensively measured health status) and criterion validity (the extent to which SF-36 correlated with existing measures of health) were established during this developmental stage. In adapting the SF-36 health assessment questionnaire for use in the United Kingdom minor changes to wording were necessary as outlined in table 3-1.

Table 3-1. Adaptation of the SF-36 original US version for use in the UK

• As a measure of distance 'block' is replaced by 'half a mile and 100 yards' as appropriate.
• In the energy and vitality domain, 'pep' is replaced by 'life' and 'low' as an indicator of energy level.
• In the context of susceptibility to ill-health 'ill' is used instead of 'sick'

Two versions of the SF-36 were adapted for use in the UK namely the Developmental and Standard UK versions. The only difference between each is the number of response choices for the second social functioning item; six for the

Developmental version and five for the Standard version. The standard version has been most widely used in the UK and was selected for use in this study. Permission to use the questionnaire in this study was provided by the Rand Corporation, Santa Monica, USA. Normative data are published for UK (Jenkinson, Coulter and Wright, 1993) and US (Ware Jr, 1993) populations and will be used to compare the scores obtained in the study subjects after CABG surgery section 6.7.1, tables 6.9 and 6.8 respectively. Although there are many generic health status questionnaire, such as the Nottingham Health Profile (McEwen, 1988) and the Sickness Impact Profile (Bergner, Bobbitt, Carter and Gilson, 1981), the SF-36 questionnaire has been widely tested in normal populations and CHD patients groups and found to be an acceptable outcome measure for use within the NHS (Garratt, Ruta, Abdalla, Buckingham and Russell, 1993). In addition because the measure would be used in a CHD patient population i.e. prior to CABG surgery and then following surgery, a time point at which it was anticipated that there would be return to full health then the SF-36 questionnaire seemed most appropriate for both these assessments.

3.9.6 Validity and reliability of the SF-36 Questionnaire

The validity and reliability of the SF-36 has been confirmed in a large number of studies of general population samples and of a variety of patient groups in the United States (McHorney, Ware Jr, Rogers, Raczek and Lu, 1992; McHorney, Ware Jr, Raczek, 1993). The scientific review criteria are based on eight attributes namely: conceptual and measurement model; reliability; validity; responsiveness; interpretability; respondent and administrative burden; alternative forms; and cultural and language adaptations (Lohr, Aaronson, Alonso, Burnam, Patrick et al, 1996). Previous work utilising health status measures have found that they may be unable to detect clinically important changes for individuals whose health is either very poor or very good. These have been referred to respectively as 'floor' and 'ceiling' effects. These were reported in the summary statistics as the percentage of respondents scoring the lowest possible score (floor effect) and highest possible score (ceiling effect).

A study that investigated the use of the SF-36 in a general population included 216 older adults (age > 65 years) found that there was a high degree of internal

consistency for each scale item. The evidence for construct validity was good with the score distinguishing between those with and without clinical evidence of poorer health (Lyons, Perry and Littlepage, 1994b). The authors attributed their high completion rates to administration of the questionnaire in an interview setting. This conclusion was supported by work investigating the use of the SF-36 in an elderly population in comparison with the Euroquol scale (Euroquol Group, 1990) for 380 females older than 75 years old participating in a study investigating the efficacy of a therapeutic agent. The health status scales were found to be in general agreement with each other and evidence that construct validity against age and recent use of health services. However, the SF-36 achieved lower levels of completion of individual items within the instrument leading to inconsistency problems. The authors suggest that this may be overcome by adaptation of the scale for use in an elderly population or use interviewer administration.

3.9.7 Limitations of SF-36

In any health assessment instrument that aims to be comprehensive but short inevitably there are by necessity areas that are not included. In this case measures of health distress, sexual functioning, family functioning and sleep adequacy are not directly explored. In addition the instrument does not directly base its view of health on lay perspectives of health although, in use, it does collect information from patients as opposed to judgement the of health professionals directly. In the context of this study the latter limitation was addressed by the addition of patient reports on their health experience collected within the qualitative interviews.

3.10 Health Locus of Control

The concept of locus of control originated in the theory of social learning whereby an individual's experience in a given situation led to the development of specific expectancies (Rotter, 1954). These expectancies were subsequently shown to influence future behaviour. Individuals considered to be 'internals' were more likely to take steps to improve their environmental conditions than 'externals' (Rotter, 1975). The scale was developed to examine the relationship between health-related locus of control and health behaviours and was designed for use as a measure of the 'degree of internal and external control'. A number of statements (n=34) described

as being 'face-valid' measures of generalised health expectancies were constructed, each evaluated on a six point scale. The statements were constructed to ensure that a balance between items worded in the 'internal' and 'external' direction was maintained. Comparison with other validated scales was employed in the selection and testing of questions (Wallston et al, 1976). From the original 34 statements, 11 items were selected for the final scale resulting in a possible score within a potential range of 11 to 66. Construct validity and functional utility of the HLOC scale were confirmed during the development and instrument testing phases of the study (Wallston et al, 1976). The literature described use of the HLOC scale in small groups of individuals only. However, the MONICA project (Glasgow centre) used an adapted version of this measure with four response options instead of six. Because data were available (kind permission of Dr Caroline Morrison) on the responses more than 1000 individuals from a similar geographic area it was decided to use this version of the HLOC scale. This allowed comparisons to be made between the study subjects and the MONICA subjects. Statistical advice was sought and was approved because the new scale was simply a linear re-scaling of the old scale, that is, no value-dependent distortion of the statistical content was involved.

3.11 Social Activities Questionnaire

The social activities questionnaire was developed as a measure of social well-being in the Rand Health Insurance Experiment (Lohr et al, 1986a; Lohr, Brook, Kamberg, Goldberg, Calabro et al, 1986b). It was based on the concept that social well-being had two distinct dimension related to quality and quantity. Quantity was concerned with the number of contacts and the amount of activity whereas the quality dimension was concerned with personal evaluations of the meaning and satisfaction of interpersonal relationships. The selection of questions was based on the adaptation a number of existing instruments (Donald and Ware, 1982;), to meet a range of specified criteria including conceptual relevance, variability in score distribution, repeatability and sensitivity to the effects of medical care (Myers, Lindenthal and Pepper, 1975; Donald Ware, Brook and Davis-Avery, 1978). Item scaling was accomplished by examining the relationships between responses to each item and the three variables of emotional ties, psychological well-being and current health.

There are 11 items in the scale covering social contacts, group participation, social activities and subjective evaluation of the quality of relationships. Response categories can be converted into scale scores for each item. An overall summary index of social support was calculated using 10 of the 11 items (item 7, relating to letter writing, was excluded because it showed no relationship to the criterion variables outlined above). Reliability and validity has been tested within the HIE studies on more than 4000 adults. Test-retest reliability was established within studies where repeat measurements were made on a time scale of one-year intervals. The construct validity of individual items is supported by their relationship to the criterion variables employed in the scaling procedure and through associations between measures and predictions of mental health (Williams, Ware, Donald, 1981; Donald and Ware, 1982). Permission to use the questionnaire in this study was provided by the Rand Corporation, Santa Monica, USA.

3.12 Justification of methods

The rationale for linking qualitative and quantitative data has been described as 'expanding the breadth and scope of the study (Greene, Caracelli and Graham, 1989). Methodological triangulation was used to allow for an examination of issues that were known to be important in the area of study and to explore new areas. An interview format was chosen for both baseline and follow-up assessment as the most appropriate manner to collect the data necessary to answer the research questions and to improve completion rates of the self-administered questionnaires. Consideration was given to the format and content of the questions and the style of responses that would be appropriate. The structured interview was based on pre-set questions that were asked in the same manner for all subjects to standardise interpretation and elicit the appropriate responses. In this study the self-complete questionnaires used in both phases of the study were compiled contain the validated questionnaires described and to collect the additional information required to allow the research questions to be answered. Questions were kept as short as possible to convey the essence of the area of enquiry and the frame of reference of the study. The format of the questions varied and included use of rating scales, closed questions, open questions and a simple form of the critical incident technique. The question style was selected in order to collect data that was meaningful to the issue under enquiry.

3.13 Validity and Reliability

External validity relates to the generalisability of the research findings to other settings and other sample groups. Characteristics of the sample group should be clearly representative of those of the target population in order for the results to be externally valid. Internal validity is concerned with competing explanations for the same results. For example, could the results have occurred by chance, or by some other mechanism that has not been taken into account. Reliability of the measure or questionnaire being used is concerned with its ability to obtain the same results when used repeatedly whereas validity is a measure of the tool ability to accurately assess the area under enquiry (Oppenheim, 1992).

In terms of factual questions reliability was assessed through a number of internal checks by the inclusion of questions that explored the same areas e.g. limitation of functional status as a result of angina symptoms and cross-checking with medical records for accounts of medications were included. Validity of the responses to factual questions was dependent on the willingness and ability to retrieve the required information. The questions were constructed using short sentences and clear language avoiding the use of technical words. Testing for clarity during the pilot phase was undertaken with the opportunity to intimate areas that were unclear provided to improve the validity of responses. Discussion of reliability and validity of health status measures and instruments published by other authors were discussed in the relevant sections.

Chapter 4

4.1 Materials and Methods

4.1.1 Introduction

This chapter outlines the procedures and methods that were undertaken in the preparation and conduction of this study in order to address the research questions. The main contents included are ethical approval, subject selection, recruitment procedures, instrumentation employed, preparation and administration of questionnaires and the conduction of interviews and clinical assessments.

4.2 Research questions

- What is the health status in broad terms of subjects prior to CABG surgery?
- What is the health status in broad terms of subjects following CABG surgery?
- What aspects of pre-operative health status are associated with changes in health status post-operatively?
- What are the expectations of benefit from surgery from the patient perspective?
- How do the patients report the experience of CABG surgery?

In order to answer these questions the study was designed to describe the health status of individuals before and after CABG surgery. Health status was considered in terms of five distinct perspectives namely,

- quantitative estimates of health states as measured by the short-form-36 health assessment questionnaire
- self-rated estimates of angina symptoms using rating scales
- health states as determined by the presence or absence of CHD risk factors
- socio-economic status, health locus of control and social networks.
- subjective accounts of health and expectation and experience of CABG surgery

4.3 Design and Plan of Study

The design was that of a prospective cohort study, employing methodological triangulation that included quantitative and qualitative research approaches. The study cohort was assessed at two time points; that is before (approximately four weeks) CABG surgery which is Phase I of the study and again approximately 15 months later which is Phase II of the study. The follow-up time period of 15 months was selected to allow to all patients to be assessed at phase I of the study, have their operation and have a sufficient time to recover from the surgery and get back to normal life. Interpretation and analysis of results employed descriptive and correlative statistical techniques for the quantitative data and thematic analysis for the qualitative data. The key stages of the study and its timetable are outlined in figure 4-1.

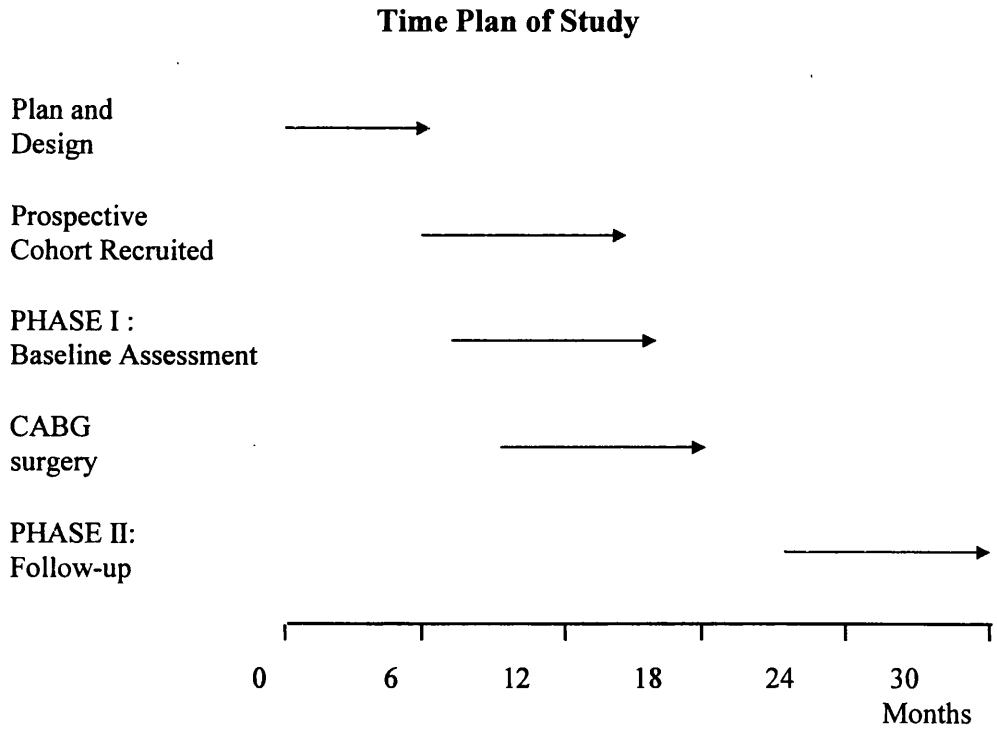

Figure 4-1. Design and time plan of study.

4.3.1 Subject Selection

Patients awaiting CABG surgery were identified from the waiting list held within the computerised COMPASS record system at Glasgow Royal Infirmary NHS Trust. A

purposive sample (n=215) was recruited over a six month period according to the following inclusion criteria:

4.3.2 Inclusion criteria

- Single CABG procedure
- Elective category
- Residence within approximately 50 miles radius of the hospital centre.
- Expected date for surgery was estimated to be approximately 4 weeks ahead (no date had been allocated at that time point or at the time of interview, so only an estimate was possible).

4.3.3 Research Setting

A dedicated room in the Outpatient Department was available for the duration of phase I of the study. Phase II of the study was conducted in the subjects' home unless a hospital visit was requested (this option was used for a small minority of the subjects <10).

4.4 Ethical Approval

Concerns at an international level, about protection of the rights of human subjects who participate in research studies led the World Medical Association to develop guidelines enshrined in the 1975 'Declaration of Helsinki'. These encapsulate key ethical precepts of autonomy, beneficence and non-malevolence (Singleton and McLaren, 1995a). These principals require that the benefits, risks and justifications for any research are both scrutinised by external review and evaluated by autonomous, informed participants who have had the both the opportunity to reflect upon the implications of the research and to request clarification of issues where necessary (Singleton and McLaren, 1995b). An application for ethical approval was prepared and submitted to the Ethics Committee at Glasgow Royal Infirmary NHS Trust. Written permission to contact patients was received from Consultant Cardiologists and Consultant Cardiac surgeons. Ethical approval was granted (Appendix I).

4.4.1 Informed Consent

Informed consent has been defined as 'a voluntary uncoerced decision made by a sufficiently competent or autonomous person, on the basis of adequate information and deliberation, to accept or to reject some proposed course of action which will affect him/her' (Singleton J and McLaren , 1995b). Subject recruitment was carried out in accordance with this definition and the elements of informed consent as outlined by Singleton and McLaren (Singleton and McLaren, 1995b), p13. A written patient information sheet and consent form was prepared (Appendix II) to provide details of the study and implications for the patient should they consent to participate. Patients were advised that their usual care would not be influenced or changed in any way as a result of participating in the study. At any time after commencing the study subjects could withdraw without any affect to their usual care. The subjects were assured that the information collected would be available only to the researcher and the project supervisors and that their privacy and anonymity would be ensured (Singleton and McLaren, 1995a). It was explained to the subjects that data collected during the study would be entered onto computer database and access, confidentiality and security maintained according to the regulations outlined under the Data Protection Act (Data Protection Act, 1984).

4.4.2 Ethical considerations

Ethical approval was granted prior to the commencement of the study. The study was undertaken within a prospective observational design and attention was taken by the researcher not to introduce any bias or fundamental change to the management of the subjects. However, particularly in research studies that include vulnerable patients, ethical conflicts may arise between the rigour of the method employed in observational studies, which are non-intervention by design, and the professional and ethical issues of clinical practice (Singleton and McLaren, 1995a). Within the Professional Codes of Conduct are enshrined the principles of beneficence and non-malevolence (United Kingdom Central Council, 1992). This charges healthcare professionals to act positively for the well-being and benefit of their patients and 'to do them no harm'. Upon such principles are founded the therapeutic relationship of trust between nurses, doctors and the recipients of care, who assume their best interests are always considered first. Subjects were advised that although the

researcher was a nurse, in the context of the study, was not providing nursing care but would refer any problems or issues that arose to the relevant clinician who was responsible for the patients' ongoing healthcare, if this was deemed necessary.

Patients had been assigned to a waiting list for surgery for a period of several months and high levels of anxiety both for the patients and their families could be anticipated. Sensitivity to these feelings was always a consideration during any communication with the subjects and extreme care was taken not to persuade or influence the patients in their decision to take part in the study or at any other time during the study. Because the patient's cardiac condition may be severely limiting, this was seen as a major consideration in terms of causing additional hardship through requesting an additional visit to the hospital. Furthermore, deterioration in health might have occurred during the time period since admission to the waiting list. In an attempt to address these issues only patients who were categorised as 'elective' cases and not 'emergency' cases were identified to avoid contacting those patients who were likely to be the most severely ill. In phase II of the study, many patients reported disappointment because they were still experiencing symptoms and therefore sensitivity to their feelings was an important element during any contact the researcher had with the patients. One patient refused to take part in the follow-up interview because of his disappointment at the result of the CABG surgery.

Patients expressed concern in relation to the long waiting time they had experienced and in particular, the uncertainty of a date for surgery. On these occasions, patients were asked to consult their GP with regard to obtaining more information about the likely date for surgery. When specific arrangements had been made by the Cardiac Surgeon for the patient to communicate with the secretarial staff in relation to their position on the waiting list, patients were directed to continue in that manner. There were no circumstances when the date for surgery was changed as a direct result of participation in this study.

When lifestyle CHD risk factors were present, such as smoking and obesity, general health advice based on minimal intervention was reinforced to ensure the patients were aware that these were additional risk factors and that they should be working towards making changes prior to surgery. The relevant health education booklets

available within the outpatient clinic were provided for patients to reinforce and supplement information provided during the interviews.

When clinical measurements were abnormally high, as well as listing these details in their medical notes, permission was sought from the patient to contact their General Practitioner and an appointment arranged for reassessment. On one occasion blood pressure readings were so high that medical staff at Glasgow Royal Infirmary NHS Trust were contacted and treatment initiated at that time.

Often patients requested more information about their surgery. Clarification of the details of CABG surgery procedure and an explanation of the process of care that was likely to happen when patients were admitted to hospital were provided after the clinical assessments and structured interview had been undertaken. Two patients who were extremely anxious and uncertain about the operation were referred to the Cardiac Rehabilitation nursing staff for more detailed counselling. No specific written details or advice were given to the patients when they were seen by the cardiac surgeon. However, leaflets published by the British Heart Foundation and the Health Education Boards in clinic areas are available and patients may be directed to them or choose to take this written information.

4.5 Phase I: Preparation of data collection tools

4.5.1 Introduction

The data collection tools for phase I of the study, that is, the baseline assessment of health and well-being prior to CABG surgery were constructed in the following formats; a set of questionnaires, designed to be completed by the subject; a clinical assessment record to document demographic details and clinical measurements; and a structured interview schedule.

4.6 Self-complete questionnaires

The self-complete questionnaires consisted of three assessment tools previously described namely SF-36 (Stewart and Ware, 1992) (Appendix III), health locus of control (Wallston et al, 1976) (Appendix IV), and social networks (Donald et al, 1978) (Appendix V). In addition a fourth questionnaire developed for the study

consisting of open and closed style questions focusing on healthy lifestyle behaviour intentions and degree of severity of angina and breathlessness symptoms using two rating scales were prepared as described in section 3.8.

The rating scale used was a horizontal line anchored at each end by terms that represent the extremes of symptoms experienced as a result of angina pain and breathlessness. The two symptoms assessed were that of chest pain and breathlessness on self-rating scales based on a 0 to 7 range where 0 represented 'no effect on your overall well-being and health' and 7 represented 'complete disability, discomfort and restriction to life'. Respondents were asked to indicate the intensity of the sensation at that moment in time by placing a point across the scale. The explanatory details for completion were brief and simple. The scores were assessed by measuring the distance between the lowest point and the respondent's mark. To facilitate completion a short introduction was provided to guide the respondent in answering the self-complete questionnaires. The self-complete questionnaires for phase I of the study are contained in Appendix VI.

4.7 Phase I Clinical assessment and structured interview schedule

A clinical assessment record was prepared to collect the following information; demographic details (date of birth, gender, postcode), blood pressure level, body weight and height, waist measurement, smoking habit, physical activity, current medications, personal and family history of CHD and employment type and status. Plasma cholesterol levels would be documented in this record when the results were reported usually five to seven days after the test. Additional free space was provided to allow the researcher to compile field-notes during and after the interviews. A section was also provided for collation of data pertaining to the cardiac surgery procedure. The structured interview schedule to guide the interview was prepared based on three open questions to explore the subjects' view of their health and their expectations of CABG surgery. The clinical assessment record and structured interview schedule for phase I of the study are contained in Appendix VII.

4.8 Pilot Phase I

4.8.1 Subject Recruitment

Following receipt of ethical approval, a letter was sent to patients who met the selection criteria providing a short explanation of the purpose of the study and inviting those patients who wished further details and/or were interested in participating to reply (Appendix VIII). A pre-paid return envelope was included. Initially five patients were contacted in order to pilot the study method and all agreed to come to the hospital to meet with the researcher and hear more about the study.

4.8.2 Subject consent

Patients who indicated that they interested in knowing more about the study were given an appointment date and time agreeable to them. On arrival the patient was welcomed and a more detailed overview of purpose of the study and implications of involvement for them. Informed consent was formally obtained in written form (Appendix II); all patients who attended agreed to participate. Names and addresses of General practitioner, Consultant Cardiologist and Cardiac Surgeon were noted in a study record for each patient with their address and telephone number and date name was added to the CABG surgery waiting list. The interviews were conducted at the Outpatient Department, Glasgow Royal Infirmary NHS Trust, where a dedicated clinical interview room was available for the duration of the study.

4.9 Administration of self-complete questionnaire

The self-complete questionnaires were given to the patient prior to the clinical review and structured component of the interview and allowed to complete the questionnaires in the interview room. Some patients were accompanied by a relative and they were invited to stay. Patients were allowed time to complete the questionnaires, and the time was noted at start and on completion (to the nearest 5 minutes) a time which ranged from 25-40 minutes.

The self-complete questionnaires were collected from the patients and comments were invited concerning any difficulties that experienced in answering the questions and in general terms how relevant the questions were in assessing their particular health and well-being status. Comments were noted and clarification of questions

provided whenever required. Care was taken not to interpret the question for the patient but through simple repetition and example, support was provided to help in answering.

4.10 Clinical assessment and structured interview

4.10.1 Clinical assessment

An explanation of the measurements that would be made was provided. The subjects were asked to provide details of tobacco smoking either current or past and the type and level of exercise they were able to undertake. Details of their own history of heart disease and that of their family (first degree relatives) were collated. Current medications were recorded. The clinical assessment was undertaken as described in sections 4.10.2, 4.10.3, 4.10.4.

4.10.2 Blood pressure

Patients had at this point been seated for more than 20 minutes in accordance with British Hypertension Society guidelines (Sever et al, 1993). Blood pressure was recorded using a mercury syphgmomanometer. The instrument was dedicated for use in this study to exclude inter-instrument variations and calibration checked at the Department of Medical Physics, Glasgow Royal Infirmary. An appropriate sized cuff with velcro fastenings was applied to the upper left arm after ensuring that there were no restrictions due to tight clothing. The cuff was placed at the same level as the heart. The arm was allowed to rest on the adjacent desk. The cuff was deemed appropriately sized when it was possible to ensure that the cuff bladder would encircle the majority (at least 80%) of the circumference of the arm as recommended (Petrie, O'Brien, Littler and De Swiet, 1986). Small (9 X 18 cm), medium (12 X 23cm) and large (15 x 33 cm) cuffs were used as appropriate to meet the recommendations for accurate measurement of blood pressure. The column of the mercury manometer was placed in the vertical position. The patients were advised that two measurements would be taken with an interval of five minutes between recordings. The cuff was inflated to occlude the radial pulse and then deflated at approximately 2mm/sec. Korotkov phase I was taken as the systolic blood pressure and Korotkov phase V was taken as the diastolic blood pressure each measured to the nearest 2 mm Hg. An average of the two recordings was used in the analysis.

4.10.3 Anthropometric indices

Body weight was measured to the nearest 0.1kg in light clothes with outdoor clothes and footwear removed and height to the nearest 0.1cm. Portable weighing scales were used for this project to allow for their use in the follow-up part of the study that would be conducted in patient's own homes. The weighing scales were dedicated for use only in this study to avoid overuse and the possibility of introducing inter-instrument variation by using other scales was avoided. Body mass index (kg/m^2) was calculated as weight (kg) divided by height squared (m^2). Waist measurement was recorded as the smallest circumference between the rib cage and the iliac crest and was measured to the nearest 0.1cm with a flexible tape (World Health Organisation, 1989).

4.10.4 Plasma cholesterol measurement

In order to be able to measure blood levels of cholesterol and lipoproteins patients require to fast for 12 hours prior to the sample being drawn. Following discussion with the patients relating to the feasibility of fasting for such a time, together with the requirement of taking several medications in the morning, it was clear that this was not a practical or desirable option. The other option of fasting and delaying medication until after clinic appointment was also not considered safe practice. As a result patients were advised to have breakfast and take medications as usual and a non-fasting blood sample would be collected for cholesterol measurement. A venous blood sample was collected from the anti-cubital fossa area of the arm in the following way. A tourniquet was firmly applied to the upper arm (a pressure that still allowed for arterial blood flow to be maintained) to allow veins to engorge and to help identify a suitable vein to access to obtain a blood sample for cholesterol measurement. The tourniquet was released immediately venous access had been gained to minimise venous stasis, which can alter biochemical components within the blood. A 10 ml blood sample was collected into a sample tube containing the anticoagulant EDTA. All cholesterol analyses were performed at the Institute of Biochemistry, Glasgow Royal Infirmary NHS Trust using standardised protocols with Internationally agreed quality assurance procedures.

4.10.5 Structured interview

The measurement of clinical variables was now complete and patients were offered a hot drink. Information pertaining to the measurements that had been recorded was provided and a general discussion then continued in relation to how they were feeling on that day and their usual day-to-day activities.

The purpose of the structured interview was explained as a general introduction followed by open questions outlined in the schedule. The interview continued in an informal manner and the subjects were advised that all information collected, would be treated confidentially. Commentary was encouraged through attentive listening, and appropriate body language reflecting the sentiments expressed as recommended by Collins (1988). The structured interview provided an opportunity for subjects to expand on their feelings about their general health and focus on the key areas of importance to them within the whole experience of living with CHD and awaiting CABG surgery. It was explained that short notes would be made to document comments made during the discussion and that they would be asked at the end of the interview, to verify that an accurate record of the issues raised had been collected. This process acted as a 'member check' in establishing the credibility of the interview findings (Polit and Hungler, 1997).

It was decided, in conjunction with the study supervisors, that in view of the large volume of data that would be generated as part of the quantitative part of the study, in practical terms the interview data should be 'condensed' at the time of collection in the form of memos. This has been described as an integral part of the planning and data collection process (Miles and Huberman, 1994). As far as was possible, the words and phrases expressed by the patient were noted. Clarification and of the meaning of issues raised was employed, as appropriate, and was useful in maintaining the continuity of the interview.

The process of memo taking, in the context of qualitative research methods, has been described as 'the writing-up of ideas about codes and their relationships as they strike the analyst while coding' (Glaser, 1978). This usually takes place at the first 'sifting' of raw fieldnote texts as the key concepts are identified within the data. In this study memo taking was employed within the process of fieldnote recording. As far as

possible words and phrases were recorded in the patients own words to minimise interpretation errors. The nature of the dialogue in terms of the ease with which the patient talked about their feelings and the issues that were important to them was noted together with general observations of emotions evoked as the interview took place. Clarification and re-checking of the comments noted during the interview with the patients was done to ensure as much as possible that their comments had been accurately summarised. This part of the interview lasted approximately thirty minutes.

4.11 Evaluation of pilot Phase I

The methodology employed to pilot the feasibility and practicalities of conducting the study was undertaken in the first five patient recruited to the study. It was evident that the time necessary to conduct the study in the manner outlined was considerably longer that anticipated. In particular, the self-completed questionnaires required a longer time period for the subjects to complete varying from 25 minutes to 40 minutes. In addition, it was felt that in some cases, patients appeared to be rushing in order to complete the forms as quickly they could. The latter pages of the battery of questionnaires had least attention paid to them as evidenced by a greater level of omissions. This may be because the questions were less clear but feedback such as 'is this enough sister' seemed to indicate that they had reached saturation; a feeling that was confirmed on direct enquiry.

4.12 Changes to protocol following pilot phase I

On the basis of the pilot it was decided to mail the questionnaires at the same time as the patients' appointment confirmation. Instructions to complete the questions as best they could were included and patients were advised that areas where they were unclear could be left to be discussed and the questionnaires completed at the clinic visit. The consent form was mailed at the same time and completed when the attended for interview. A limitation of this approach was the inability of ensuring that the study participant was the sole contributor to the questionnaire. Because of the possible effect of less attention being paid to the latter pages, to improve rate of completed instruments, the individual instruments that depended on several pages

were placed at the beginning i.e. the Short Form-36 (Stewart and Ware, 1992). The social network scale (Donald et al, 1978) consisting of one page was placed at the end.

4.13 Phase I Main Study

The alterations to the study design on the basis of the pilot phase were firstly to re-order the individual questionnaires within the self-complete set of questionnaires as outlined above. Secondly it was decided to mail the self-complete questionnaires to the subject prior to the clinic appointment so that they could be completed ahead the clinical assessment and structured interview. Extra copies of the self-complete questionnaires were available for subjects who had misplaced or lost the originals.

Subject recruitment was conducted prospectively with approximately 20 letters posted per week. A follow-up telephone call was made if there was no response after two weeks to establish if the letter had been received and to provide further details about the study for those who indicated an interest. Recruitment was ongoing and continued at the same time as the implementation of the first phase of the study and continued until the target of 215 was reached. Response rates were collated. Subject consent was undertaken as in the study pilot. The preparation of the data collection tools, the clinical assessment and structured interviews were conducted in main study as outlined for the pilot phase.

4.13.1 In-Hospital: Procedure, Intensive Care Unit and General Ward

In order to identify when patients were time tabled for surgery the theatre lists for surgery were requested. These were compiled in the latter part of the preceding week and available within a few days of the proposed surgery date. As a result patients often had very little notice of their operation date and it also made it difficult to plan ahead in order that the researcher could visit the patients during their stay. In addition last minute cancellations even after the patients had been admitted did arise, in most cases due to beds in intensive care unit (ITU) being unavailable. This situation arose when patients following surgery required longer support in ITU beyond the usual 24 hours stay. However, this situation only arose in a very small minority of the study patients.

Data were collected from the medical notes on the following aspects of the patients' surgical experience. The broad details of aspects of the procedure carried out in terms of number of grafts inserted, use of the internal mammary artery, time on cardiopulmonary bypass, cross clamp time, length of overall procedure and any adverse events recorded during the course of the operation.

Length of stay (hours) in intensive care was recorded in the medical records of each patient and this was noted together with any adverse events recorded particularly in relation to extended stay in unit. Length of hospital stay (days) was collected after each patient was discharged and a note made of any adverse events during their stay. In hospital mortality cases were identified and cause of death recorded.

Visiting the patients during their hospital stay was an important opportunity to maintain contact, which the researcher considered to be important to reinforce the value that was being placed on their contribution and of the significance and purpose of the study itself. At this time the patients were reminded that they would be contacted again in approximately 15 months later and although they were under no obligation to continue if they so chose. It was explained that as part of the follow-up review part of the study the researcher would be interested on their reflections of both the current experience and that to come over the intervening time. It was thought that this served to heighten their awareness of the many diverse events, feelings and encounters ongoing throughout this time. Patients were given contact numbers and addresses and asked if they could inform the researcher if they were changing their address and/or telephone number or changing their general practitioner.

4.14 Phase II: Preparation of data collection tools

4.14.1 Introduction

The data collection tools for phase II of the study, that is, the follow-up assessment of health and well-being after CABG surgery were constructed in the following formats; a set of questionnaires, designed to be completed by the subject; a clinical assessment record to document clinical measurements; and a structured interview schedule.

4.14.2 Phase II Follow-up Period

A follow-up period of a minimum of one year post-surgery was selected in order to allow comparison with other studies that have reported outcome at one year following surgery. The follow-up period ranged from 13 to 18 months post-surgery, with an average follow-up period of 16.4 months. The follow-up period extended beyond one year and this was a result of the requirement for completion of Phase 1 of the study. In addition, because only one researcher was involved in the data collection and the lack of availability of some patients at the start of Phase 2 of the study, a follow-up period of greater than one year was necessary.

4.14.3 Self-complete questionnaires

The self-complete questionnaires consisted of three assessment tools previously described namely SF-36 (Stewart and Ware, 1992) (Appendix III) health locus of control (Wallston et al, 1976) (Appendix IV) and social networks (Donald et al, 1978) (Appendix V). In addition, a fourth questionnaire was developed for the study and consisted of questions to evaluate uptake of cardiac rehabilitation based on the critical incident technique (Cormack, 1996), hospital re-admission, return of angina or breathlessness and degree of severity of angina and breathlessness symptoms using two rating scales as previously described in section 3.8.2. This self-complete questionnaire for phase II of the study is contained in Appendix IX.

4.15 Phase II Clinical Assessment Record and structured interview schedule

A clinical assessment record was prepared to collect the following information; blood pressure level, body weight, waist circumference, smoking habit, physical activity, current medications, and employment status. Plasma cholesterol levels were documented in this record when the results were reported usually five to seven days after the test. The structured interview schedule to guide the interview was prepared based on two open questions to explore the subjects experience of having undergone CABG surgery and their views on their current health and well-being. A copy of the clinical assessment record and structured interview schedule are contained in Appendix X.

4.15.1 Post -CABG surgery follow-up of study subjects

Prior to contacting the patients to arrange an appointment for phase II of the study, that of the review of health and well-being 15 months after surgery, the general practitioner was contacted to establish that the patient was still alive according to their records. The health centre was contacted by telephone to obtain clarification that the patient had not died in the intervening time since their operation. There were a small number of patients who had moved out of the geographical area. The original health centre where the patient had been registered was able to provide details of the new health board area to which their patients had moved. The Health Board Registrar staff were able to supply the name and address of the general practitioner with whom the patient was now registered. It was then possible to establish if the patient was still alive. Patients who could be contacted by telephone were telephoned and an appointment for a home visit arranged. The remainder were contacted by letter with a pre-paid reply envelope and asked to provide some possible dates for the review visit. Details of patients who had died since surgery or moved from the area and not contacted for further assessment, or declined to take part were collated.

4.16 *S*elf-complete questionnaires

The self-complete questionnaires (Appendix IX) were posted to the subjects approximately one week prior to the arranged appointment date. The questionnaires were collected at the time of the phase II assessment that took place in the subject's home in the majority of cases.

4.17 Pilot Phase II Clinical assessment and structured interview

4.17.1 Introduction

Phase II of the study was piloted on the first five patients contacted at a time point approximately 15 months following surgery. The mechanism of checking that the subjects were alive, through contacting their general practitioner was satisfactory and reliable.

4.17.2 Clinical assessment

An explanation of the measurements that would be used was provided. The subjects were asked to provide details of tobacco smoking either current or past and the type and level of exercise they were able to undertake. Current medications were recorded. The clinical assessment was conducted as described in phase I (section 4-11) of the study for blood pressure level, body weight, waist circumference and plasma cholesterol level. The setting for the assessment in phase II of the study was the subjects' home. One patient preferred to come to the hospital outpatient clinic for the second interview and this was agreed. The home setting was chosen to allow the subjects to be able reflect on their views and thoughts within familiar context of their own home environment.

4.17.3 Structured interview

After completion of the clinical assessments and information relating to the measurements was provided, a general discussion continued relating to how they were feeling on that day and their usual day-to-day activities. The structured interview then followed on from this according to the schedule and attention to the principles of interviewing discussed in phase I of the study. The time taken for structured interviews was noted (to the nearest 5 minutes) and lasted approximately 30 minutes.

4.18 Phase II Main Study

There were no changes to the study protocol or instruments used following the pilot stage of phase II of the study. The timescale in which this part of the study was implemented was at least one year and no more than 18 months after CABG surgery. The follow-up assessments were carried out over a time period of approximately 9 months according to the methods described for the pilot of Phase II study (section 4-15.1). In order to standardise the follow-up time period for re-assessment, the surgery date was used to dictate the order in which patients were contacted. Subjects who had their CABG surgery earliest were therefore contacted first and the others contacted sequentially.

4.19 Data Analysis: statistical techniques

4.19.1 Introduction

In this section the statistical techniques that are used in this study to describe and evaluate the data that were collected are outlined. Data were entered onto a computer database and all statistical calculations were done using SPSS (version 6) (Norusis, 1994).

4.19.2 Continuous and discrete variables

The observed variables can be grouped into two main categories; they are either discrete or continuous variables. Discrete variables are characterised by a prescribed set of distinct values. Gender is a discrete variable and for the purpose of analysis has been assigned the value 1 for males and 0 for females. Continuous variables can have any value within a given range. Examples of continuous variables are blood pressures or weight. The validity of a statistical operation will depend on the status of variable.

4.19.3 Mean

The "sample mean" of the variable X, denoted by $\overline{X}$, is the most commonly used summary statistic and is the sum of the values of all the observations in the sample divided by the sample size. However, different samples may have different sample means, although it can be shown that as the sample size increases, the sample mean progressively approaches a fixed number μ, the mean of the population from which the sample is drawn. Statistically significant changes in the sample mean of a particular variable are commonly used to detect the benefits (or otherwise) of surgery.

4.19.4 Variance and Standard Deviation

The "variance" of a sample is used to describe the spread of sample observations about the sample mean and is calculated by summing the square of the difference between each observation of the sample and the sample mean, and then dividing this sum by the "number of degrees of freedom" possessed by the sample. If the sample itself is used to compute the sample mean then the number of degrees of freedom is one less than the size of the sample. On the other hand, if the population mean is

given *a priori* (i.e. not estimated from the sample), then the number of degrees of freedom possessed by the sample is simply the size of the sample.

Since the variance describes the spread of a sample about its mean, samples with a large variance are well spread out while those with a small variance are tightly clustered around the mean. The "standard deviation", which has the same units as the sample mean, is defined as the square root of the variance and is commonly quoted along with the sample mean and the size of the sample in descriptive statistics. The three taken together provide the basic description of the sample. In addition, the "standard error" of the sample mean is often quoted and is defined as the standard deviation of the sample divided by the square root of the sample size. This is the standard deviation of the distribution of the sample mean about the population mean and is a crucial parameter in testing the significance of changes in the mean value.

4.19.5 Median and quartiles

The median of a sample is that value of the random variable such that equal numbers of observations lie above and below it. In fact, the median is a more robust estimator of the average value of a population than the sample mean, failing only when a sample has large numbers of outliers unlike the sample mean which can be over sensitive to small numbers of outliers (defined in the next paragraph).

A sample may be further subdivided into "quartiles" by first decomposing it into two sub-samples consisting respectively of all those observations that lie below the sample median and all those that lie above the sample median. The median of each sub-sample together with the median of the full sample now partitions the observations into quartiles. Therefore one quarter of the sample observations lie in the lowest or 1^{st} quartile, another quarter lie in the highest or 4^{th} quartile while the remainder (one half) lie in the 2^{nd} and 3^{rd} quartiles. The distance between the lower boundary of the 2^{nd} and the upper boundary of the 3^{rd} quartile is called the interquartile range. Observations that are more than three interquartile ranges below the lower boundary of the 2^{nd} quartile or above the upper boundary of the 3^{rd} quartile of a sample are called "outliers".

4.19.6 The Normal distribution

The Normal or Gaussian distribution is the most common (continuous) distribution. It is completely specified by its mean μ and variance σ^2 and is an example of a parametric distribution. Many variables, referred to as "normal deviates", used in this study may be approximated by a normal distribution. For example, figure 4-2 displays a histogram of baseline (phase I) waist circumference for the male subjects (n=170) of this study. Superimposed on this histogram is a normal curve with mean 96.9cm and standard deviation 8.09cm, the mean and standard deviation of the male waist measurements. Clearly the waist measurements are well approximated by the normal distribution.

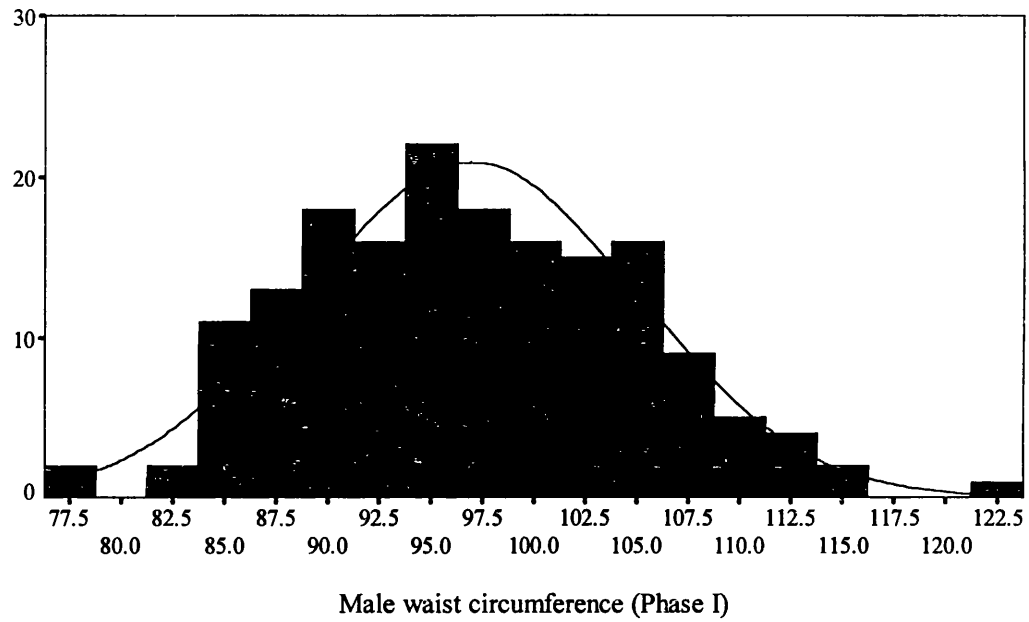

Figure 4-2. Histogram of waist measurement (cm) for males at phase I assessment.

The fact that under very general circumstances, the sum of a large number of independently distributed random variables approaches a normal distribution, gives this distribution a pivotal rôle in statistical analysis. This observation is formalised in the central limit theorem of statistics. The importance of this result for the current study is that one can safely assume that the sample mean of samples containing as few as 25 observations will be acceptable for statistical testing, provided that these

samples are not strongly skewed. In this study, 170 male and 45 female subjects were surveyed. No evidence was found to suggest that any of the samples were seriously skewed, and so it is anticipated that both the male and the female cohorts are of adequate size to test statistical hypotheses.

4.19.7 Hypothesis testing

During this research, individuals were surveyed before surgery (phase I) and after surgery (phase II) so that the complete set of observations contains a large amount of paired data for each subject. One objective of the study was to assess whether or not there has been a significant change in phase I measurements at phase II assessment after surgery. This issue is addressed by testing the "null hypothesis", denoted by H_0, that samples taken at phases I and II are but two samples drawn from the same population, i.e., there is no difference between the mean of these samples. Of course, such samples cannot be expected to have the same mean or variance, but by recognising that the sample mean behaves like a normal deviate and using the fact that the difference of normal deviates is a normal deviate, it is possible to assign a "confidence level" to H_0. If H_0 is rejected, the samples are assumed to have come from different populations. Consequently one may conclude that the surgical intervention had an effect on this variable. By convention, H_0 is accepted at the 95% confidence level, if two samples drawn from the same population are identified as coming from that population 95 time out of 100. This means that on average there is a chance of one in twenty that the null hypothesis will be rejected when in fact it is true, i.e., there is a 5% probability (p-value=0.05) of rejecting H_0 when it is true. If a comparison of the means of paired samples gives a p-value of less than 0.05 then the difference is said to be statistically *significant*, if the p-value is less than 0.01 then the different is said to be statistically *very significant* and if the p-value is less than 0.001 then the difference is said to be statistically *highly significant* (Dunn, 1964).

4.19.8 Student's t-distribution

Often the variance of the population is unknown and is replaced by the variance of the sample. In this case, the normal distribution is replaced by the Student's t-distribution. This distribution is very similar to the normal distribution with the same mean except that it is flatter in the central hump and has a correspondingly greater

probability in its tails (Daly, Bourke and McGilvray, 1991). Thus the 95% confidence level for the t-distribution allows more variability in sample means. All comparisons of paired samples of continuous random variables was done using Student's t-distribution.

4.19.9 Wilcoxon rank sum test

The Wilcoxon two sample rank sum test (or equivalently the Mann-Whitney U test) is used to compare paired samples in which the random variable takes a small number of discrete values. In this study, the number of risk factors (blood pressure, plasma cholesterol, BMI etc.) above prescribed critical levels (ranges from 0 to 5) is an example of such a discrete variable. For this type of random variable, the sample mean has no interpretation as a random variable and so the use of a t-test is problematic. Instead, tests are performed by ranking or ordering the observations in the two sample from lowest to highest. Repeated observations are assigned an average rank. The Wilcoxon test statistic for each sample is now calculated by summing the ranks of the individual observations in that sample. Using Wilcoxon tables, the difference in ranks between the two samples is translated into a p-value (Daly et al, 1991).

4.19.10 Chi-squared test

The χ^2 test is used to compare two samples using a statistic that takes two values only, for example, dead or alive. Accepting H_0, namely that the two samples are drawn from the same population, the samples may therefore be combined and the combination used to estimate the expected number of subjects in each of the two categories for each sample. A χ^2 table with four compartments is now built in the form of a 2 x 2 matrix. Each row of this matrix corresponds to a sample and each column corresponds to a category of the statistic. The χ^2 statistic for each compartment is now calculated by squaring the difference between the observed and expected number of subjects in that compartment and then dividing by the expected number of subjects in that compartment. The χ^2 statistic for the entire table is formed by summing the χ^2 statistic of the four compartments. Tables of χ^2 values with one degree of freedom are now used to extract a p-value (Kenkel, 1989).

4.19.11 Multiple Testing

In the process of analysing a large number of independent hypotheses tests, each with a significance level selected at 5%, then even in the absence of any real effects, some of the tests would be significant by chance. This problem becomes more likely with the larger the number of tests. This effect is the result of a type one error and a simple method of correcting for it is known as the Bonferroni correction (Campbell and Machin, 1994). The basis of the correction can be summarised as follows:- in conducting n significance tests, with an overall type I error rate of α, then any one of the individual tests would only be declared significant if the p-value was less than α/n, thus if five hypotheses were tested within a single analysis, then instead of a significant level based on a p-value less than 0.05 for any one of the tests, it should be adjusted to a p-value of <0.01. In effect this means that it is more difficult to demonstrate statistically significant results when multiple analyses are being performed. In the analysis undertaken in this thesis this correction was not undertaken. However, in order to take into account of its effect, p-values of borderline significance, for instance p-values of the order of 0.04-0.05 should be interpreted with caution.

4.19.12 Regression

Regression is a procedure by which a model is constructed connecting a single dependent variable, Y, and a series of predictor variables $X_1,\ldots, X_n$ (Wonnacott and Wonnacott, 1981). For example, Y might be an SF-36 domain score at phase II while the predictor variables $X_1,\ldots, X_n$ could be SF-36 domain scores, blood pressures, deprivation category, angina and breathlessness scores, age etc. at phase I. The first issue to be addressed in any regression analysis is to decide what predictor variables (from the many possibilities available) best describe the behaviour of the dependent variable. Often an understanding of the underlying processes helps to eliminate unreasonable variables. In any event, the most significant predictor variables can usually be identified from a bivariate correlation table constructed from the dependent variable Y and an extensive list of possible predictor variables. Every correlation coefficient has an associated p-value that depends on the size of the correlation coefficient and the size of the sample. Large correlation coefficients (around 0.15 in magnitude in this study) correspond to predictor variables with p-

values less than 0.05, that is, variables that potentially have a significant impact on the value of the dependent variable *Y*. Positive correlation coefficients indicate pairs of variables that trend in the same direction whereas negative correlation coefficients suggest pairs of variables that trend in opposite directions (i.e. when one increases, the other decreases).

In the absence of evidence to the contrary, *Y* is assumed to be a linear function of the *X*'s including a possible arbitrary constant. Such a model is commonly called a "linear regression". The null hypothesis for a linear regression assumes that the coefficients of the regression are zero. The analysis of the regression assigns a p-value to each coefficient, the null hypothesis for that coefficient being rejected whenever its p-value is less than 0.05. Variables with coefficients not significantly different from zero do not feature in the regression and are excised. The regression of systolic blood pressure against diastolic blood pressure, age and diabetes is now used as an example of a regression analysis.

4.19.13 Systolic blood pressure

Phase I systolic blood pressure *Y* when regressed against the phase I variables diastolic blood pressure (X_1), age (X_2), the presence of diabetes (X_3) and the number of risk factors above critical threshold (X_4) gives the regression formula

$$Y = -10.33 + 1.21X_1 + 8.08X_2 + 0.68X_3 + 2.14X_4 .$$

The regression analysis is based on 186 subjects and the p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are

Variables	constant	X_1	X_2	X_3	X_4
p-value	0.315	<0.001	0.005	<0.001	0.012

The regression analysis also returns an adjusted R^2 value of 60.5%. Roughly speaking, this may be interpreted as the percentage of the variation in *Y* that is explained by the regression. An R^2 value of unity (100%) means that the entire

variation in *Y* is explained by the regression, whereas "small" R^2 values indicate that the regression explains very little of the behaviour of *Y*. The criterion of acceptability is context dependent. The dependent measures used in this study are notoriously variable. Adjusted R^2 values range from 13.5% to 26% and are regarded as acceptable in a study of clinical and health characteristics of individuals, although in other disciplines, these values may be regarded as too low to be useful.

Evidence to support the contention that this is a reasonable regression comes in two parts, both of which revolve around the properties of the residuals, defined as the difference between *Y* and the prediction of *Y* using the regression. These residuals must be normally distributed and have a variance that is independent of the predictions of the regression. This can be checked by a histogram of the standard residuals with a superimposed normal distribution as shown in figure 4-3.

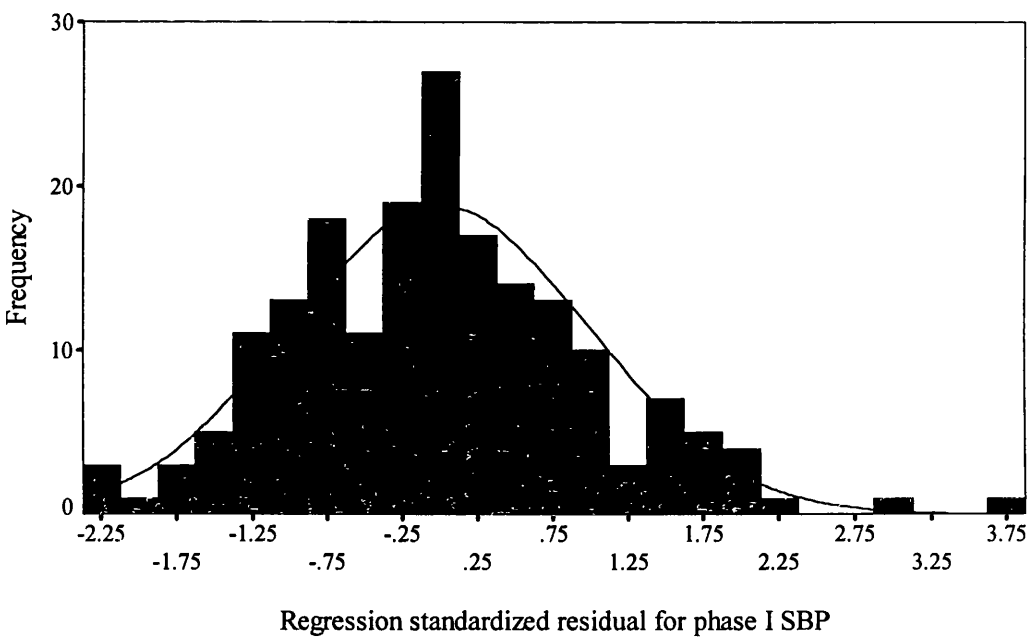

Figure 4-3. Standardised residuals for systolic blood pressure measurement at phase I when regressed against age, diastolic blood pressure, diabetes mellitus and number of CHD risk factors with superimposed curve showing a normal distribution of mean zero and variance of the standardised residuals.

Alternatively, the exact normal cumulative distribution can be plotted against the sample cumulative distribution in a normal P-P plot as demonstrated in figure 4-4.

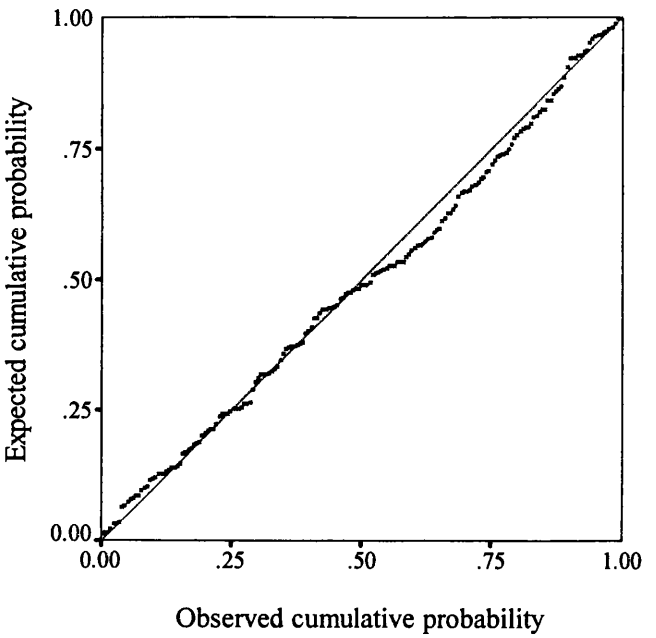

Figure 4-4. Normal P-P plot of the expected cumulative distribution of the standardised residuals against the observed cumulative distribution.

If the residuals are approximately normal, the normal P-P plot will be approximately a straight line.

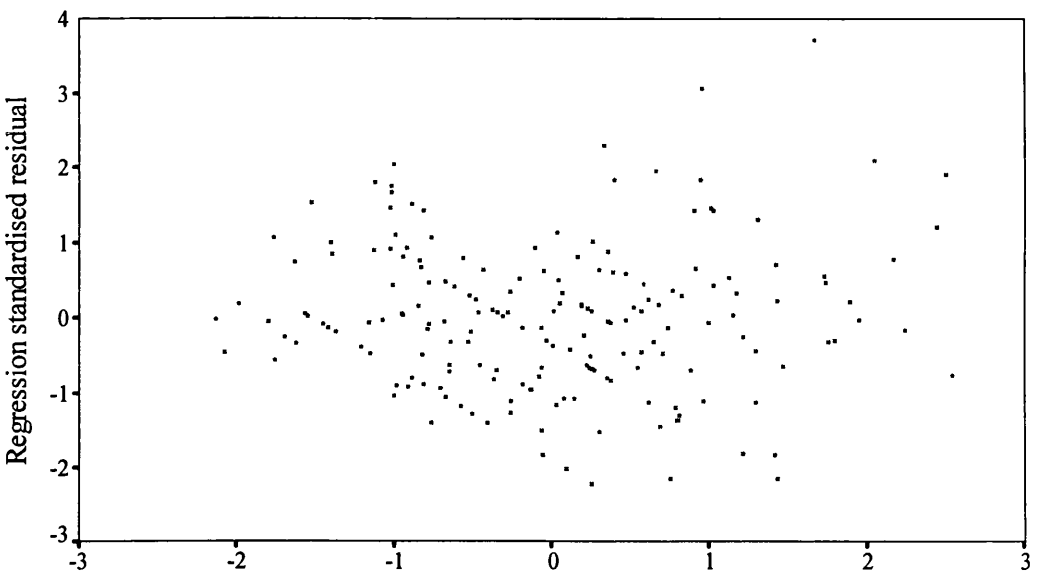

Figure 4-5. Scatterplot of the residuals versus the predicted values for systolic

blood pressure measurement a phase I

Finally, a scatterplot of the residuals versus the predicted values is required to demonstrate that the variance of the residuals is independent of systolic blood pressure as predicted by the regression. This is presented in figure 4-5 and shows that there is a random distribution of points and therefore independent relationship between the two variables. This diagram exhibits no obvious trends or banded structure that typically arises in a poor regression, that is, a regression in which the residuals are clearly dependent on the fitted values.

4.20 Power Calculation

The primary end point used to assess outcome following CABG surgery was the difference in the SF-36 scores across its eight health domains. Published data for mean SF-36 scores in populations with CHD and normal populations were examined to estimate the likely difference than would be expected between pre- and post-operative assessments. Across the eight health domains the changes in scores ranged from 10 to 25. Based on an estimated 5% change in score, the sample size required to demonstrate a change of this size, with 80% power, on a one-sided test was estimated to be 200 (Ware, Snow, Kosinski and Gandek, 1993). In order to take account of an estimated follow-up attrition rate of between five and ten percent the target number of subjects to be included in the study was therefore 215.

4.21 Data analysis: Interview data

4.21.1 Qualitative data

It was decided in view of the already large volume of data that would be generated as part of the quantitative part of the study that in practical terms the interview data should be 'condensed' at the time of collection in the form of memos. As far as was possible, the words and phrases expressed by the patient were noted. Data reduction has been described as an integral part of the planning and data collection process (Miles and Huberman, 1994). The process of memo taking, in the context of qualitative research methods, has been described as 'the writing-up of ideas about codes and their relationships as they strike the analyst while coding' (Glaser, 1978). This usually takes place at the first 'sifting' of raw fieldnote texts as the key concepts

are identified within the data. In this study memo taking was employed within the process of fieldnote recording.

Data reduction therefore continued from the initial phase when the field of inquiry was outlined to that of memo summaries. The next stage in the management of the qualitative data involved writing up the memo fieldnotes which in many cases contained abbreviations, short hand sketchy details and hand-writing that in some instances would be fairly illegible for anyone else to attempt to read.

Thematic analysis involved the search and identification of common threads that extended throughout the entire set of interviews. Themes have been described as concepts instigated by the data rather than concrete entities directly described by the participants (Morse and Field, 1996). The first task is to read and re-read the interviews in their entirety and, through writing memos and notes, summarise the interviews, keeping in mind that more than one theme may exist. Themes are significant concepts that link portions of the interview together and link interviews from the various correspondents.

The analysis of the qualitative data continues with a search for themes or recurring issues commonalties and natural variation within the data. A further step involves validation of the understandings that the themes have provided to ensure that the themes inferred provide an accurate representation of the perspectives of the subjects interviewed. Member checks, i.e. presentation of the preliminary thematic analysis to a sample of the subjects for confirmation or contradiction was carried out as recommended in this data collection process (Miles and Huberman 1994).

The depth of the data analysis will depend upon the researcher's sensitivity, perceptions, informed valued judgements, insight and knowledge. The purpose of qualitative research is not to determine objectivity, i.e. what actually happened, but rather to objectively report the perceptions of each of the participants in the setting. Theoretical verification was achieved in two ways. The first is verification of the findings with the participants of a research study and secondly, verification with the related literature and with practitioners with expertise and knowledge of the health

issues of individuals with CHD. An example of confirmation of themes and verification is included in Appendix XI.

4.21.2 Qualitative and quantitative data

As suggested by Rossman & Wilson (1991) qualitative and quantitative data were linked for two main reasons. Firstly, to elaborate and develop analysis thus providing richer detail, and secondly, to explore new lines of thinking through attention to unexpected findings and paradoxes to provide fresh insight into the health status of patients before and after coronary artery bypass surgery. Qualitative data provided rich depiction of the cases in the study, thereby overcoming the abstract and depersonalised information gained through quantitative methodologies. Several designs have been developed in order to link quantitative and qualitative data (Miles and Huberman, 1994). As suggested in this summary of designs, quantitative and qualitative data were collected in a continuous integrated approach to facilitate understanding of each particular subject in the study.

4.22 Presentation of results

A large volume of data was generated during this study and the researcher has recognised that these data may be presented in a number of different ways. The results are presented according to the sequence in which the study was conducted. The data collected also offered a number of different ways in which analysis could be undertaken. However, as a primary objective the analyses performed were directed by the information required in order to answer the research questions.

The main strategy was to present the data for the whole study cohort as a single group. However, for important clinical variables, results are examined for males and females separately to take into account important gender differences in CHD and CABG surgery outcome that have been reported in the literature. A range of statistical tests, depending on the analysis and the type of variable, has been used and are described in section 4-20. These have been noted throughout the presentation of the results.

A summary of the variables measured and their abbreviations are contained in Appendix XII. Correlation analyses were based on an examination of all variables with relationships that showed positive or negative correlations or were statistically significant presented. The correlation analyses were used to identify all potentially significant variables. However, all variables were initially included in the regression analysis that was performed in a step-wise fashion. The final regressions were based on only those variables whose coefficients were found to be statistically significant. For clarity a summary of key points are presented at the conclusion of each of the results chapters 5, 6 and 7.

Chapter 5

5.1 Results I: Baseline characteristics of study cohort

5.1.1 Introduction

The data in this chapter were collected during the baseline assessment at phase I of the study. Data collected beyond this stage and during the follow-up, phase II, are presented in Chapters 6 and 7. When appropriate, the data are described for the total study cohort, and for the male and female subjects separately. When comparisons between continuous datasets were made, student's t-test was used to establish if the samples were statistically different. The baseline data are grouped into discrete areas namely; demographic and clinical characteristics; CHD risk factors; general health status and symptomatic ratings; health locus of control and social networks; and self-report health views and expectations of surgical outcome.

5.1.2 Age and sex distribution of subjects

The study cohort comprised 215 subjects in total and was subdivided into 170 (79.1%) male and 45 (20.9%) female patients all of whom had been identified from the waiting list for CABG surgery. One female was incorrectly assigned to this list as she was awating cardiac valve surgery. The study cohort therefore consisted of 214 subjects with ages ranged from 39.9 to 79.3 years with mean age 58.19 years and SD 7.7 years and 79.4% (170) males and 20.6% (44) females. The age of female subjects ranged from 44.7 to 79.3 years with mean 60.1 years and SD 8.1 years while that of male subjects ranged from 39.9 to 74.4 years with a mean of 57.7 years and SD 7.5 years. The age profile of the male and female subjects was not statistically significantly different ($p = 0.083$).

5.2 Comparison of age and gender with CABG patient groups

5.2.1 Local comparisons

The total number of patients undergoing elective CABG surgery at Glasgow Royal Infirmary as a first and single procedure was 748 during the nine months period (April 1995-January 1996) that the first phase of the study was undertaken. The study subjects represented a consecutive sample of all patients who underwent

CABG surgery meeting the criteria of a first operation with no other procedure performed at the same time.

The mean age of the study subjects compared to the total patient group having CABG surgery at the Glasgow Royal Infirmary Centre over the same time period was highly significantly younger, (58.2 years v 60.7 years, $p<0.001$). The ratio of males and females in the study group and the Glasgow Royal Infirmary patients was (79.4% v 77.4%, males) and (20.6% v 22.6%, females) which was not statistically different. It was not clear why the study subjects were younger than all the patients undergoing surgery, as no selection by age was undertaken. Patients were identified who lived within reasonable travelling distance of the hospital (approximately a 30 miles radius) although the total patient group will include patients from other areas of Scotland, for example Dundee and Dumfries. It could be that the younger patients from the West of Scotland area represent a group of patients with more severe disease that is characterised by greater symptomatic severity at a younger age. This difference has implications for the extent to which the results based on the subjects within this study are generalisable to other patient groups in other areas of practice. Generalisability of the findings of the study is discussed in section 8.14.

During 1995 (year in which CABG surgery performed), demographic data on all patients undergoing CABG surgery in the two Cardiac surgery centres within the Greater Glasgow Health Board (GGHB) area were used to check if the study cohort was representative of this larger unselected group of patients (by kind permission of Dr John Wormesley, GGHB). The GGHB population consisted of 1628 patients composed of 1211 (74.4 %) males and 417 (25.6%) females. The proportion of males and females in the study cohort is similar to that of the GGHB population. However, when the mean age of males and females in the study cohort was compared to that of the GGHB population, the mean age for males was 57.7 v 59.1 years ($p<0.001$) whilst the mean age for females was 60.0 v 63.7 years ($p<0.005$). Thus the mean age of the male and female sub-cohorts in the study, although not appearing to be very different, was in fact statistically significantly lower than the GGHB CABG surgery population. A comparison of socio-economic deprivation patterns of the

study subjects with the total number of patients from GGHB who underwent CABG surgery are presented in section 5.4.

5.2.2 National comparison of CABG patients and study subjects

National statistics indicated that 3,943 subjects underwent CABG surgery during 1995 (Report of the Great Britain and Ireland Cardiac Surgery Register, 1996). The national sample had a mean age of 61.65 years, SD 9.96 and a male to female ratio of 79.8% to 20.6%. The male to female gender balance in the study cohort was 79.4% to 20.6% and was not significantly different from the national sample (p=0.889). However, the mean age of subjects in the study sample was 58.19 v 60.65 years which was highly significantly lower (p<0.001) than that of the national sample.

5.3 Time period on waiting list for CABG surgery

The waiting time for subjects in the study was measured as the elapsed time (in days) between their name being assigned to the list for surgery to the date of surgery. The profile of waiting times are presented in Figure 5.1.

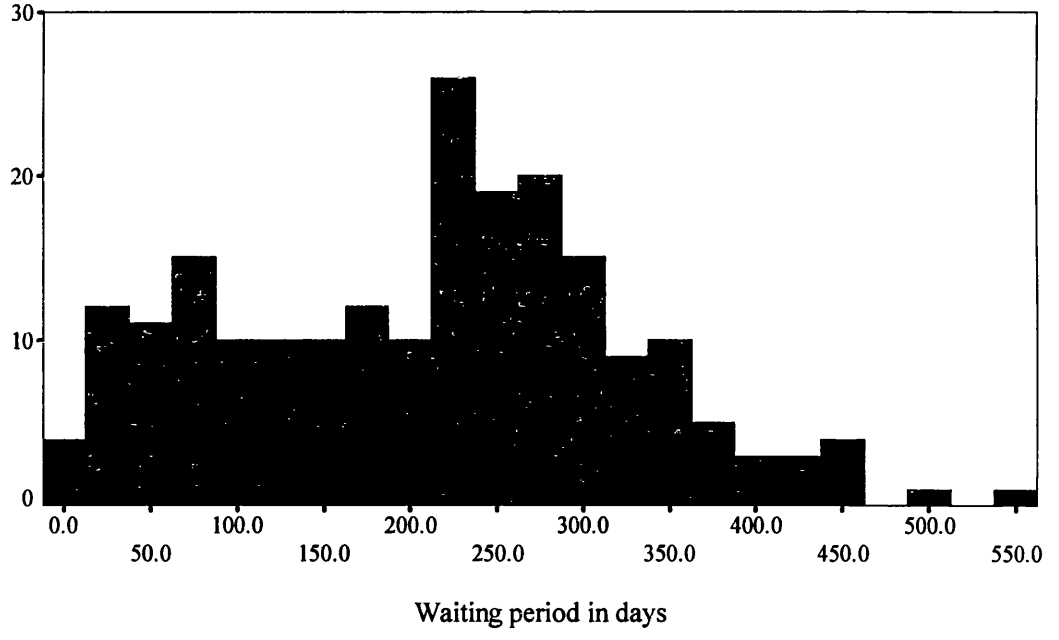

Figure 5-1. Time period on the waiting list for CABG surgery in days

The median time period on the waiting list for the subjects (n=210) who underwent surgery was 224.0 days with a minimum of 6 days and a maximum of 550 days.

5.4 Socio-economic deprivation

The socio-economic deprivation categories of the study cohort, as measured by the Carstairs classification, are presented in table 5-1 as percentages of subjects in each of the deprivation categories 1 to 7 together with the GGHB patient deprivation categories. The classification is "1" for the least deprived and "7" for the most deprived category. The study cohort for both males and females were from more deprived areas compared to the total GGHB patient data set using the Mann-Whitney test. This difference was statistically significant ($p<0.001$). This was not an unexpected finding, given that the study cohort was drawn from more impoverished areas of Glasgow, whereas the GGHB patient data are from the whole city population.

Table 5-1. Percentage of study cohort and (GGHB patient population) in each of the socio-economic deprivation (Carstairs classification) categories for males and females (Mann-Whitney test)

	Carstair deprivation category						
gender	1	2	3	4	5	6	7
male %	3.5 (5.5)	4.1 (8.0)	24.1 (16.9)	15.9 (23.8)	15.3 (16.9)	17.1 (15.8)	20.0 (13.0)
female %	2.3 (7.0)	11.4 (9.1)	6.8 (14.1)	27.3 (20.4)	6.8 (14.6)	13.6 (20.9)	31.8 (13.9)

5.5 Clinical history

A clinical history of angina symptoms was reported in 98% of the sample group prior to CABG surgery. The remaining subjects who did not have clinical symptoms of angina were undergoing CABG surgery on the basis of angiographic findings as a result of an investigation of a high risk family history (n=2) and post myocardial infarction (n=2).

Assessment of the severity of symptoms as a result of CHD was made by two independent means. The first was an assessment by the physician according to the NYHA grading system (Criteria Committee of the New York Heart Association, 1974) and the second was by the subject self-assessment rating of angina pain and

breathlessness. The NYHA angina symptomatic grading assessment was documented in the subjects medical records for the majority of subjects (85.2%). The grading of angina symptoms was divided approximately equally between grade 2 (40.7%) and grade 3 (42.6%) representing moderate levels of symptom severity. There were no patients graded at grade 1, the mildest level and only small number (1.9%) at grade 4, the most severe level. Almost two-thirds (63.2%) of the subjects had a previous history of a myocardial infarction at some time longer than six weeks prior to the baseline assessment, while the remainder had no history of AMI (33%) or uncertain diagnosis (3.8%). The self-rated angina and breathlessness scores ranged from a minimum of 0 to a maximum of 7 in half point graduations. The subjects reported a wide range of scores (self reports) as illustrated for angina in figure 5-2.

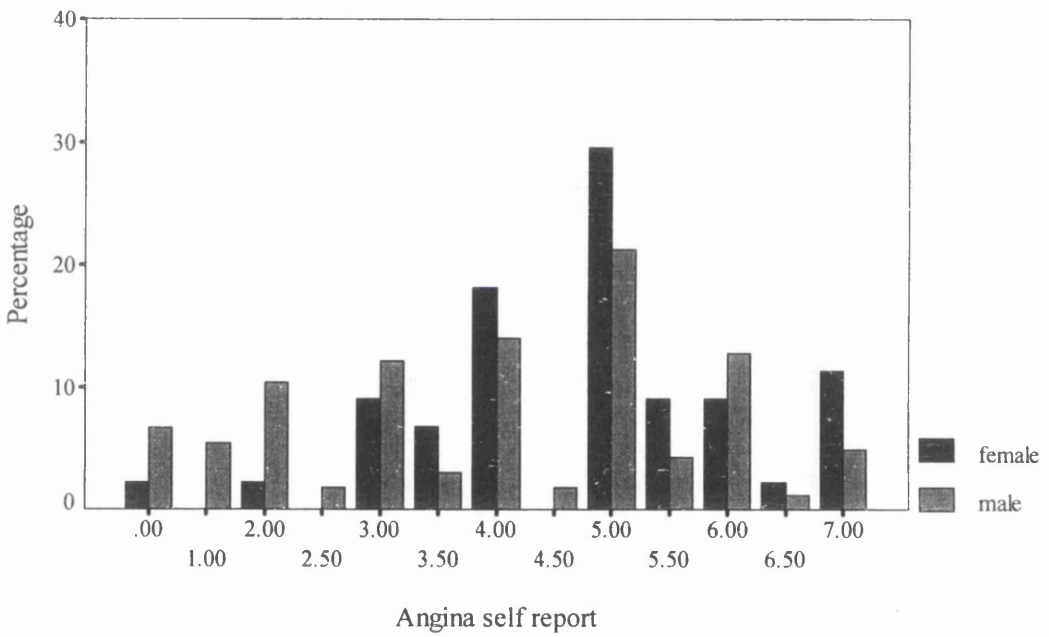

Figure 5-2. Distribution of angina self-report ratings for study subjects by gender

Mean values for the study group and for males and females are presented in table 5-2. The self-rated angina scores indicated that 5.8% of subjects reported no angina symptoms and 7.2% no breathlessness symptoms. Comparison of the mean scores for males and females using unpaired student's t-test showed that females scores were significantly higher for both self rated angina and breathlessness.

Table 5-2. Mean self-rated angina and breathlessness scores for study cohort at baseline assessment (unpaired student t-test).

symptomatic self-rated score	total group mean (SD)	male scores mean (SD)	female scores mean (SD)	p-value
	n=208	n=164	n=44	
angina I	4.09 (1.82)	3.91 (1.87)	4.75 (1.44)	**0.007**
breath I	3.78 (1.93)	3.64 (1.90)	4.32 (1.97)	**0.038**

Statistically significant p-values are indicated in bold font.

Embedded in these angina and breathlessness scores are two categories of subject, namely those who do not suffer from the symptoms (and therefore report 0) and those who have symptoms to various degrees ranging from 0.5 to 7.0. The results presented in table 5.2 do not provide any insight into the gender differences of subjects who have no angina and breathless symptoms. This limitation is addressed in the summary of symptom scores presented in table 5.3 that include only those subjects with symptoms. Female subjects experience statistically significantly higher levels of angina and breathlessness.

Table 5-3. Mean self-rated angina pain and breathlessness scores for study cohort at baseline assessment (unpaired student t-test)

symptomatic self-rated score	total group mean (SD)	male scores mean (SD)	female scores mean (SD)	p-value
angina I (+ve)	4.34 (1.56) n=196	4.20 (1.60) n=153	4.86 (1.26) n=43	**0.026**
breath I (+ve)	4.08 (1.68) n=193	3.93 (1.66) n=152	4.63 (1.64) n=41	**0.013**

Statistically significant p-values are indicated in bold font.

5.6 Correlation between angina and breathlessness self-rated scores

Male and female self-rated angina scores were highly significantly correlated with breathlessness scores ($p<0.001$). Figure 5-3 illustrated the mean angina score for a given level of self-reported breathlessness and portrays two distinct regions of breathlessness scores, namely scores of 2.5 and below and scores of 3.0 and above.

In each of these regions, the pattern of an increasing gradient in scores suggested that there is a significant linear regression between the mean self-reported angina score and breathlessness score.

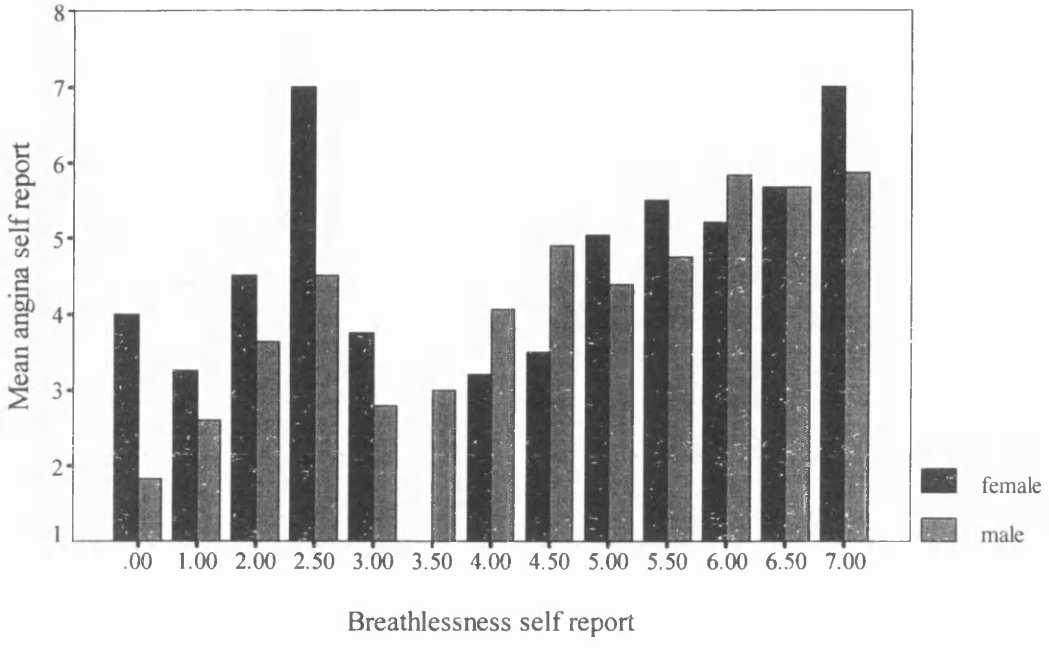

Figure 5-3. Mean self-reported angina score by self-reported breathlessness score

In the light of the highly significant correlation between angina I and breathlessness I, angina I was linearly regressed against breathlessness I and vice-versa. In both cases significant regressions were found. Specifically the linear regression:- *Angina (male)=2.352+0.484 (Breathlessness)* was calculated over 144 male subjects and explained 25.1% of the total variation in the male self-rated angina score. Both coefficients in this regression were statistically highly significant ($p<0.001$). The linear regression:- *Angina (female)=3.008+0.512(Breathlessness)* was calculated over 39 female subjects and explained 27.5% of the variation in the female self-rated angina scores. Both coefficients in the female regression were statistically highly significant ($p<0.001$).

5.7 CHD Risk Factor Assessment

The presence of the main CHD risk factors namely hypertension, hypercholesterolaemia obesity, waist circumference, presence of diabetes mellitus

and smoking status were assessed. Mean values with their standard deviations for continuous variables and percentage present for categorical variables are given in table 5-4. Male and female data are examined separately and statistical differences in measurements assessed using unpaired student t-test for continuous variables and chi-squared test for categorical variables. Statistically significant differences between males and females are indicted by their p-value in bold font.

Table 5-4. Mean levels of CHD risk factors for total study cohort and for males and females

CHD risk factor	total (n=214) mean (SD)	males (n=170) mean (SD)	females (n=44) mean (SD)	p-value
DBP I (mm Hg)	81.0 (12.3)	80.7 (12.6)	82.2 (10.6)	0.487
SBP I (mm Hg)	134.7 (10.1)	133.2 (19.6)	139.3 (23.2)	0.096
Tchol I (mmol/l)	5.8 (1.2)	5.7 (1.0)	6.2 (1.6)	**0.025**
BMI I kg/m^2	28.0 (3.4)	27.7 (3.3)	28.9 (3.6)	0.565
waist I (cm)	95.7 (8.6)	96.9 (8.1)	91.0 (9.2)	**<0.001**
diabetes mellitus	12.6%	11.2%	18.2%	0.213
current smoking I	22.9%	21.8%	27.3%	0.973

Statistically significant p-values are indicated in bold font.

5.8 Presence of CHD risk factors above target levels

Guidelines for target blood pressure levels (Sever, 1993), for plasma cholesterol levels (Betteridge et al, 1993), for waist circumference (Lean et al, 1998) and for BMI (Christenson et al, 1995) were used to assess the extent to which these modifiable CHD risk factors had been addressed in the study cohort. These criteria are outlined in table 5-5 together with the percentage of subjects who had elevated CHD risk factors according to these definitions. Statistical difference in the number of males and females with CHD risk factors above target levels was examined using

chi-squared test. As can be seen from table 5-5 there were a large number of subjects who had CHD risk factors above target levels. This provides support for more intensive management of CHD patients to help achieve target levels for such correctable CHD risk factors. These data are used in the follow-up analysis to examine their effect in determining outcome health status. Statistically significant differences between males and females are indicted by their p-value in bold font.

Table 5-5. Percentages of subjects with major CHD risk factors above target levels

action level	total (percentage)	Male (percentage)	Female (percentage)	p-value
SBP > 140 mm Hg	39.0	37.3	46.3	0.287
SBP > 160 mm Hg	11.9	11.2	14.6	0.548
DBP > 90 mm Hg	30.0	32.5	19.5	0.102
DBP >100 mm Hg	9.0	8.9	9.8	0.860
Tchol > 5.2mmol/l	67.4	67.3	67.5	0.984
BMI>25kg/m^2	80.8	78.2	90.9	0.058
BMI>30kg/m^2	22.9	21.2	29.5	0.240
waist> (80cm/f 94cm/m)	69.2	63.5	90.9	**<0.001**
waist> (88cm/f 102cm/m)	36.9	30.6	61.4	**<0.001**
diabetes mellitus	12.6	11.2	18.2	0.213
current smoking	22.9	21.8	27.3	0.973

Statistically significant p-values are indicated in bold font.

The presence of multiple CHD risk factors was assessed in the study cohort as defined by the guideline criteria outlined in table 5-5 and are presented in table 5-6. The same data are presented as a pie chart in figure 5-4. The majority of study subjects had multiple CHD risk factors with approximately two-thirds with three or four CHD risk factors.

Table 5-6. Number of CHD risk factors present in the study cohort by gender

sample	no risk factors	1 risk factor	2 risk factors	3 risk factors	4 risk factors	5 risk factors
study (n=189)	3.2% (3.2%)	12.7% (15.9%)	16.9% (32.8%)	34.4% (67.2%)	28.6% (95.8%)	4.2% (100%)
male (n=150)	3.3% (3.3%)	14.7% (18.0%)	17.3% (35.3%)	34.7% (70.0%)	26.7% (96.7%)	3.3% (100%)
female (n=39)	2.6% (2.6%)	5.1% (7.7%)	15.4% (23.1%)	33.3% (56.4%)	35.9% (92.3%)	7.7% (100%)

Males and females did not have significantly different numbers of CHD risk factors (Mann-whitney U-test, p=0.0524) although this level of significance is borderline and in a larger sample this may become a significant result.

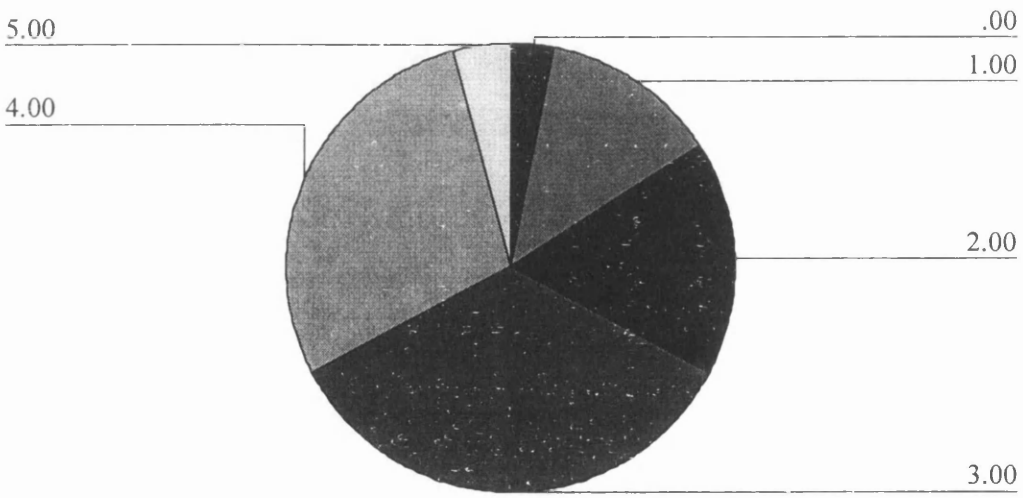

Figure 5-4. Pie chart indicating percentage of study subjects with multiple CHD risk factors

5.9 Health Locus of Control

The Health Locus of Control Scale (HLOC) scores were calculated for the study subjects and compared to scores collected as part of the MONICA epidemiological survey of cardiovascular disease and CHD risk factor prevalence (kind permission of,

Dr Caroline Morrison). The MONICA score was considered a useful basis to establish validity and reliability of the scale because the scale has not been used widely in the literature. In addition, the MONICA data were based on responses from a North Glasgow population sample, similar geographically to that of the study cohort.

The MONICA survey included responses from a random sample of 1111 individuals (591 female and 520 males) with a mean age of 45.5 years and SD 10.9 years (a younger population than the study cohort). The mean HLOC score for males was 27.2 with SD 3.5 and for females the mean score was 27.8 with SD 3.3.

The scores for the study cohort were calculated and the profile of the calculated scores presented in figure 5-5. The mean HLOC score for the total cohort of respondents (n=173) was 27.8 with SD 3.4 and range 19-40. The male scores (n=142) had a mean of 27.7 with SD 3.3 and females (n=31) had a mean of 28.2 with SD 3.8.

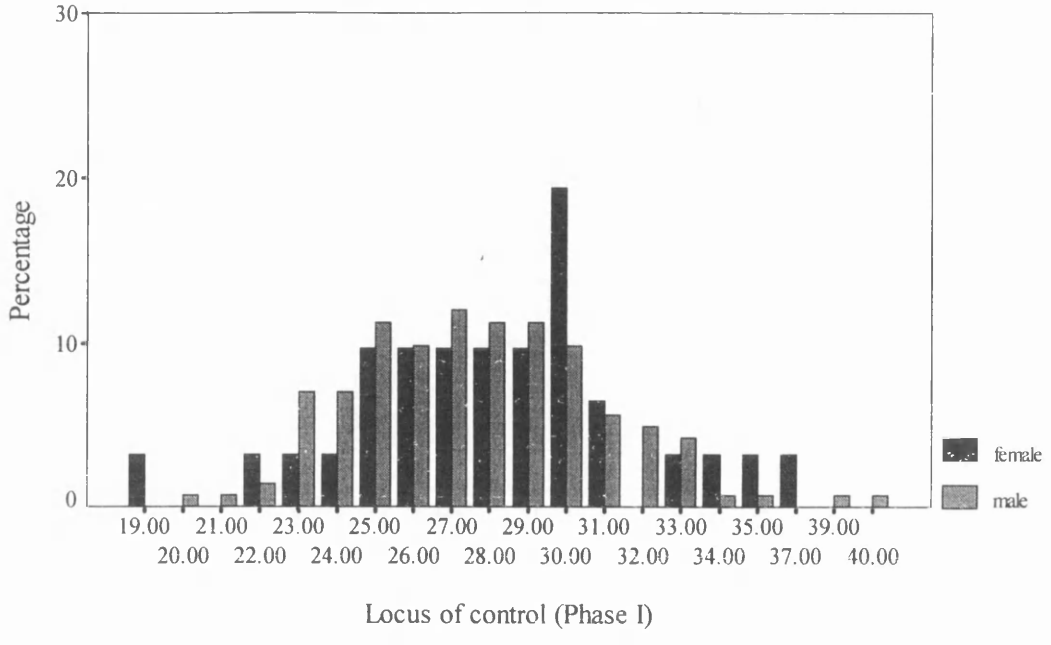

Figure 5-5. Baseline health locus of control for study cohort by gender

No statistically significant difference (p=0.341) was detected between the mean HLOC score for the study cohort and that of the MONICA sample. When the two data sets were compared by gender, again no significant difference was found between the male subjects (p=0.107) in each group and between the female subjects (p=0.571) in each group. However, gender comparisons within the MONICA sample showed that females had a statistically significantly higher score (p=0.004) than males. There were no differences in male and female scores in the study cohort (p=0.433).

Health locus of control scores were correlated (Pearson test) with deprivation category. No statistically significant correlation between health locus of control and deprivation category (p=0.424) was demonstrated.

5.10 Social Network Scores

The social network scores were calculated from the questionnaire responses returned by the majority (86.1%) of the study group (n=179). Social network scores (SOC I)

range from 8 to 40 and have the profile illustrated in figure 5-6. The mean score for the total cohort was 24.0 with SD of 7.0, for females (n=36) the mean was 23.1 with SD 7.1 and for males (n=143) the mean was 24.2 with SD 7.0. The scores for males and females were not statistically different (p=0.395).

The mean phase I social network score in this study was compared to that of the population of 4351 subjects who participated in the health insurance experiment (HIE) (Donald and Ware, 1982). The latter had a mean social networks score of 25.8 with a standard deviation of 7.97. An unpaired Student's t-test indicated that the mean score in this study was highly significantly lower than that of the HIE ($p<0.001$).

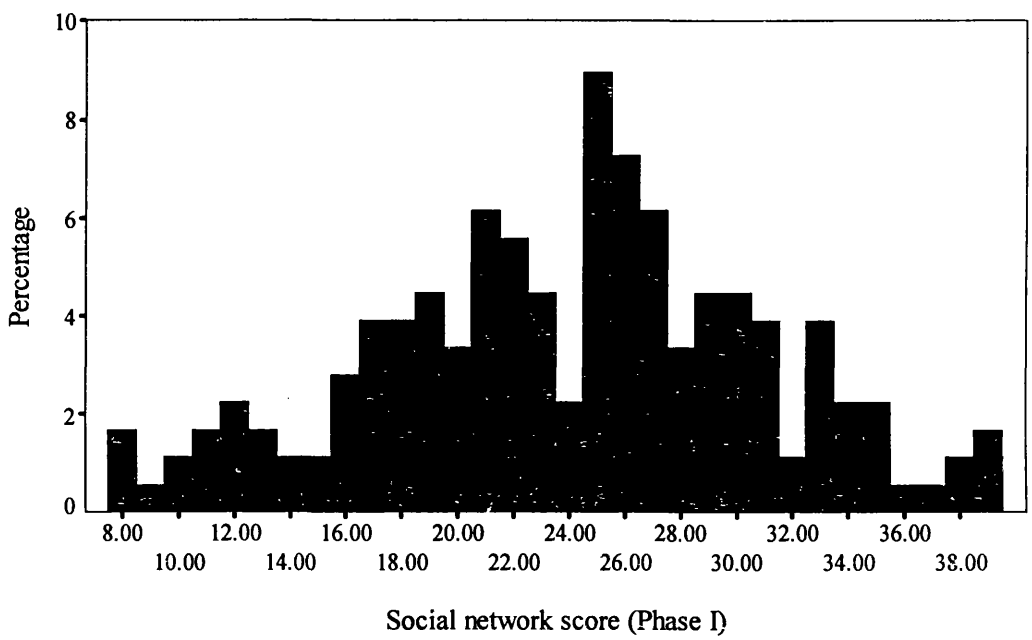

Figure 5-6. Social network scores for subjects at phase I assessment

5.11 SF-36 Health Status measurement

The responses to the self-completed SF-36 questionnaires were used to calculate scores for the eight domains of health as previously described. The abbreviations in accordance with the nomenclature of the Health Survey manual (Ware et al, 1993) are presented in table 5-7 are are utilised mainly in summaries of data contained within the appendices.

Table 5-7. Abbreviations for the SF-36 health domains

PF -- Physical Function	RP -- Role Limitation (physical)
BP -- Bodily Pain	GH -- General Health perceptions
EV -- Energy and Vitality	SF -- Social Function
MH -- Mental Health	RE -- Role Limitation (emotional)

The minimum possible score was zero and the maximum was 100 for each domain. For each SF-36-I domain, subjects' scores ranged from 0 to 100 except for general health where the range was from 0 to 75 and energy and vitality where the range was from 0 to 85. Summary baseline statistics are presented in table 5-8 and show that physical role limitation was the lowest scored health domain while mental health was the highest scored or least affected health domain. Ceiling and floor effects were evident in the role limitation due to physical factors and role limitation due to mental factors domains where respectively 70% and 50% of respondents recorded 0, the lowest possible score. As a result, these domains may be less useful as measures of health status.

Table 5-8. Summary of SF-36-I scores

SF-36-I domains	Bodily Pain	Energy Vitality	General Health	Mental Health	Physical Function	Role: Emotional	Role: Physical	Social Function
sample size	205	203	204	203	204	202	203	204
mean	44.1	35.6	36.9	61.1	34.8	37.2	14.7	47.8
25th percentile	22.2	20.0	25.0	48.0	15.0	0.0	0.0	22.2
50th percentile	44.4	35.0	35.0	60.0	35.0	0.0	0.0	44.4
75th percentile	66.7	50.0	50.0	76.0	50.0	100	0.0	67.7
std. deviation	25.9	21.1	17.1	18.7	24.1	43.6	30.9	28.3
% ceiling	3.9	0.5	2.0	0.5	0.5	28.2	8.4	6.9
% floor	3.4	4.9	0.5	0.5	7.8	52.0	76.8	4.9

5.11.1 SF-36 I scores compared to other study groups

The SF-36-I scores obtained at phase I were then compared to published scores obtained in two other CHD patient groups (Ware, 1993) and are presented in table 5-9. This was done to place the scores obtained in the study within the context of scores measured in other individuals with CHD and to compare levels of health status. Group 1 (n= 107) was a sample of males (69.2%) and females (30.8%) with a mean age of 59.2 years and a medical history of recent myocardial infarction. For all scores except that for general health, the study cohort had statistically significant lower scores implying poorer health status. The phase I general health score was slightly higher for the study cohort compared to that of Group 1 but this difference was not statistically significant. Group 2 was a sample (n= 256) of males (54.9%) and females (55.1%) with a mean age of 59.7 years and a medical history of recent angina and hypertension without myocardial infarction. All health domains measured by the SF-36 were significantly lower in the study subjects.

Table 5-9. Comparison of SF-36-I domain scores for study subjects and two groups of patients with CHD (unpaired student t-test)

SF-36-I domain	study sample mean (SD)	group 1 mean (SD) (p-value)	group 2 mean (SD) (p-value)
	(n=214)	(n=107)	(n=256)
Bodily Pain	44.1 (25.9)	72.8 (25.3) **(p<0.001)**	61.6 (24.5) **(p<0.001)**
Energy Vitality	35.6 (21.1)	57.7 (19.0) **(p<0.001)**	48.5 (20.3) **(p<0.001)**
General Health	36.9 (17.1)	59.2 (19.3) **(p<0.001)**	52.0 (18.9) **(p<0.001)**
Mental Health	61.1 (18.7)	75.8 (15.7) **(p<0.001)**	73.0 (18.7) **(p<0.001)**
Physical Function	34.8 (24.1)	69.7 (26.1) **(p<0.001)**	63.2 (26.7) **(p<0.001)**
Role : Emotional	37.2 (43.6)	73.5 (38.0) **(p<0.001)**	70.2 (36.6) **(p<0.001)**
Role : Physical	14.7 (30.9)	51.4 (39.4) **(p<0.001)**	44.2 (39.0) **(p<0.001)**
Social Function	47.8 (28.3)	84.6 (21.2) **(p<0.001)**	80.3 (23.0) **(p<0.001)**

Statistically significant p-values are indicated in bold font.

5.12 Gender Differences in responses for the SF-36 health domains

SF-36-I scores for the eight health domains were examined for significant gender differences using an unpaired student t-test. All tests involved 43 female subjects and a male sub-cohort, ranging from 159 to 162 individuals, depending on the factor under test. The missing scores typically arose because the form had not been returned or a complete page of the phase I questionnaire had been overlooked. No statistically significant gender differences were detected in the mean score for the domains energy/vitality, general health, emotional role limitation, physical role limitation and bodily pain. However, the mean female score was significantly lower than the mean male scores in each of the domains mental health, physical function

and social function. The statistically significant differences in SF-36 domains between male and female responses are presented in table 5-10.

Table 5-10. Gender differences in the SF-36-I domains (unpaired student t-test)

SF-36-I domain	number of males	male mean (SD)	number of females	female mean (SD)	p-value
Mental Health	n=160	62.7 (17.5)	n=43	54.9 (21.6)	**0.014**
Physical Function	n=161	36.6 (23.9)	n=43	27.9 (24.0)	**0.035**
Social Function	n=161	50.4 (27.6)	n=43	37.8 (28.9)	**0.010**

Statistically significant differences between males and females are indicted by their p-value in bold font.

5.12.1 SF-36-I scores in relation to angina I and breathlessness I scores

Angina and breathlessness scores were tested to examine their relationship with the SF-36-I scores. Significant negative correlations were found between angina I scores and the bodily pain (p=0.042), general health (p=0.011) and physical function (p=0.050) scores and between breathlessness I and the physical role limitation (p=0.027) score.

5.12.2 SF-36-I scores in relation to phase I variables

SF domain abbreviations are presented in (Appendix XII). The SF-36-I scores were correlated with the other variables measured during phase I assessment and are presented in Appendix XIII. Many of the correlations tested were not shown to be statistically significant. The statistically significant results are as follows:-

Deprivation category was significantly negatively correlated with bodily pain (p=0.003), energy/vitality (p=0.022), mental health (p=0.030), physical function (p=0.021) and social function (p=0.004). Subjects from higher socio-economic groups had higher scores and therefore more positive states of health in the SF-36 domains described.

Health locus of control was negatively correlated with general health (p=0.009), the more externally health orientated, the lower the health score was in that domain.

Social networks score (SOC I) was correlated positively with bodily pain (p=0.05), energy/vitality (p=0.009), general health (p=0.046), mental health (p=0.009), physical function (p=0.005), emotional role limitation (p=0.013) and social function (p=0.017). Higher social network scores are associated with greater social support and, in these correlations, were associated with more positive states of health as measured by the SF-36-I domains.

Increased waiting time for surgery was negatively correlated with the majority of the phase I SF-36 domains although physical function was the only domain to be statistically significant (p=0.006).

5.13 Structured interviews

5.13.1 Introduction

The subjects were given the opportunity to ask questions following the collection of the physiological measurements. The majority of subjects welcomed the opportunity to talk and to explore issues relating to their health in general and CABG surgery in particular. The setting and atmosphere was maintained as informal as possible within the context of a hospital out-patient clinic and the structured interview began with a summary of the purpose of the SF-36 questionnaire, as a health measurement tool. They were invited to comment on their views of its appropriateness and relevance to their health, and on any difficulty they had in the completion of the questions. The responses are presented in the limitation sections 8.11.4 - 8.11.7. Following on from the introductory question, the interview continued according to the schedule with two open-ended questions relating to the subjects' perceptions and views of their health and about their expectations of the benefits to their health following CABG surgery. A thematic analysis as outlined in the data analysis section 4-22.1 was undertaken of the responses to the interview and are described in detail in the following sections.

5.14 Health perceptions

5.14.1 Introduction

This section outlines the themes that were identified from the subject responses to enquiry about their perceptions of their health and well-being. In general the comments relating to health covered a broad range of issues relating to many dimensions of health. The all-pervading effect of heart disease on health was summarised by one subject who said that it '*affects every facet of life and the thought of having an operation .... makes me so anxious even to think about it'*. It was also clear that the views of health perceptions were influenced not only by their heart disease symptoms but the effects of knowing that major surgery was required to rectify their condition as highlighted in both the previous and following comment by one women '*did the surgeons know what a crushing blow it was to be told that I needed bypass?'*

A small minority of subjects regarded their general health to be good and didn't appreciate the need for surgery as highlighted in the following comment: *'I can't understand how my heart needs this operation, I feel fine'*. However, this was not the case for most subjects and the key issues relating to their health experience were captured within two main themes that emerged from analysis of the memos collected during the structured interview, namely; dependency and impending doom. Dependency was the most common theme to emerge from analysis of all the responses. On more detailed examination, three sub-themes were identified within the dependency theme namely; *dependency on functional status*, *dependency on others* and *dependency on medication.*

5.14.2 Dependency on physical capability

Dependency on functional capability was the most frequently raised issue by subjects in the study and different strategies in dealing with its limitations were described. Many subjects reported that they were not free to make choices about even very basic everyday activities such as visiting a friend or doing housework: *'I have to think and plan what I am doing in advance'*. This planning took the form of making an assessment of their health in terms of the level of cardiac symptoms and general tiredness at a particular moment because their capacity to cope with activity varied

considerable and was unpredictable in advance. Some subjects found it difficult to express in broad terms a view of their health and well-being because of the changeability as highlighted in the following comments: '*how I feel is variable*' ; *'I have good days and bad days'*. Some subjects described a sense of their activity being driven by their symptoms or lack of them and that they employed a strategy of undertaking activities a little at a time and continually reviewing how they felt as captured in this statement: *'I have to pace myself, hills a big problem*'. High levels of functional disability were reported by many subjects: *'can only walk about 50 yards before pain starts'*. A dependency on walking routes being relatively flat with no steps or stairs was highlighted: *'I avoid hills and inclines like the plague'*. Forward planning was reported by the majority of subjects an example of one comment was that the subject: *'never tackle unknown areas on foot'* . Detailed planning of journeys where walking would be involved was reported: '*frightened to go too far a distance walking and can't get back, get very uptight'* with one man reporting that in stark contrast to his previous disinterest in shops he now ensured that when he was planning to walk anywhere he would make sure that the route passed-by shops, so that he had an: '*excuse to stop'* or what he considered to be a legitimate reason for stopping to relieve chest pain and breathlessness. He reported feeling embarrassed at having to stop which was made worse if he was in open spaces.

5.14.3 Dependency on medication

Others reported a high degree of reliance on glycerine trinitrate spray for angina symptoms as reported by one man: '*I have to take a spray before I do anything, even washing and shaving'*. Not only was a high degree of dependency reported but also the issue of the need for forward planning where medication was undertaken in advance of activity in order to minimise worsening of symptoms or initiating chest pain. This led again to advance planning to ensure that when this cardiac medication was needed it would be close to hand as described by one subject: '*I have three sprays; in handbag, upstairs and downstairs; feel totally dependent'*. The critical role of nitrate spray was highlighted by one subject: *'It's panic stations if spray is forgotten - I'm very attached to that spray'*. The dependent effect of health on

medication was exemplified in the extent to which mechanisms were in place to avoid the risk of being unable to quickly access medication should the need arise.

5.14.4 Dependency on others

Dependency on others to take care of their usual responsibilities within the family setting was raised: *'my daughter is having her first baby, don't know how I can plan to help ; I depend on my husband and daughter to keep things going'.* In this case the subject had the additional concern of not being able to participate in supporting her daughter at a very important and special time in both their lives. Another level of dependency described by a small number of the subjects was related to adherence to medical advice: *'as long as I do what doctor says, I'll be OK',* in a broader sense that solely relating to medication. Responsibility for their health and well-being was devolved to their doctor with a sense of lack of any personal control or influence over their health status.

5.14.5 Impending Doom

The need to wait for surgery was also considered by many as an additional source of stress and had a negative effect on their general health and well-being: '*the strain gives problems of thinking and worrying'* with some subjects reporting that this was the biggest factor in how they felt in terms of: '*the waiting time is the worst problem'.* A sense that there was a fragility surrounding their very existence was a real concern which was strongly apparent in the subject accounts with comments: '*I feel that a heart attack could happen at any minute*' or *'I could die at any time'.* This was not reported as an occasional thought or concern but a fundamental fear: *'I live in fear of something happening every day',* affecting their ability to undertake basic everyday activities: *'I'm frightened to do shopping'* in case something dreadful would happened to them. These accounts give some insight into the anxiety and burden of living with heart disease and at the same time facing a long wait for an operation that to alleviate their symptoms.

5.14.6 Expectation from surgery

The second section outlines the themes that were identified from the subject responses to enquiry about their expectations from surgery. The subjects in most

cases had more comments to make in response to this question. This may be because the opportunity to discuss this area had not arisen before or had not arisen at an appropriate time or that no-one was available to listen to their expectations, fears and concerns. It became clear that a large number of subjects were unclear on the effect that surgery would have on their health: *'haven't thought of how op will help my health'*, *'don't know what surgery will do for me.'* It was not a matter that they could discuss easily with their families who were also worried about their health and well-being. Others were clear that the surgery was necessary if their health was not going to deteriorate further, if not a life saver in itself: *'would be worse or dead without operation'*. Many subjects expressed fear and apprehension about the forthcoming surgery in fairly strong terms: *'petrified of surgery'* and *'terrified of having operation'*. This was often their first time for surgery so there was a sense of facing the unknown yet an appreciation that heart surgery was a fairly serious procedure to be facing. The main themes that emerged from analysis of the memos collected during the structured interviews were *'freedom and independence;* *'hope, chance, uncertainty'* and *'years to life, life to years'*.

5.14.7 Freedom and independence

Freedom from risk of either having another myocardial infarction or, in one case, cardiac arrest: *'operation will prevent me having a cardiac arrest again'* ; *'If you don't have the operation, you are likely to have a heart attack'*. The pain of angina symptoms were portrayed as having a greater impact in terms of the restrictions they imposed as well as the pain itself : *'freedom from the pain'* , *'able to do things I haven't been able to do, like driving'* ; *'Can't walk up stairs without getting pains in chest, hope it will relieve angina pain'*. The expectations reflected a desire to be relieved of the dependency that was reported in the former question which explored perceptions of their health and highlighted that a negative aspect of their health was the enforced dependency as a result of angina symptoms. The freedom to be active and engage in activities without having to plan in advance was valued by one subject who commented that at present: *'I have to think about managing pain before going out for a simple walk'*. The removal of the threat of symptoms occurring at random and frequently was important to one subject: *'I have regular attacks out of the blue, feels like being in a prison without bars'* who alludes to a notion of captivity

imposed by the angina symptoms and the resultant freedom following surgery that was expected.

5.14.8 Hope, chance, uncertainty

During the interview the notion of hope was expressed by the majority of subjects: '*hope everything goes all right*' demonstrating a positive disposition to the future beyond cardiac surgery although combined with a feeling of entering the unknown. It became apparent during these discussions that the majority of subjects were willing to undergo surgery without having a clear view of how their health would benefit with frequent comments such as: '*might make me feel better*' ; *'not sure what to expect health to be like after operation'* . The notion of a guarantee of benefit from surgery was alluded to in the interviews with some subjects stating that they expected: 'a *guarantee of years of better health'* while others were of the opinion that there were: *'no guarantees from the operation'*. These polarised viewpoints were a common feature of the reported expectations of many subjects.

The possibility that the outcome from surgery could be unfavourable was raised by some subjects with an assessment of the likelihood or risk of this happening being made. This was cited in some cases as a specific value that was attributed to the risk of an untoward event, for example: ' *a one percent risk of something going wrong' ; 'a 50% better chance of survival'*. The uncertainty with which subjects viewed the outcome was apparent in their use of the terms *'risk'* and '*chance'*. Some subjects' evaluation of the possible benefits was based on information that had been given to them about the nature of their cardiac problem, for example, one subject reported: *'because blockage is in an awkward place, expect only 80% recovery'*. There was a general feeling that subjects were approaching surgery with feelings of uncertainty about the future: *'hope I will benefit, but no extent of benefit has been mentioned'*.

5.14.9 Addition of years to life and life to years

Evaluation of the benefit of surgery on life expectancy and the expected length of time that the surgery would provide benefit to health were often expressed together. Some comments alluded to the temporary nature of the beneficial effects of surgery: '*operation only lasts for 10 years'* with a fixed and finite time given. This view of

additional life expectancy with a specified time period cited was described by many subjects: *'the operation will add 10 to 15 years to your life'* was a common expectation with no reference to changes in symptoms, functional status or general health and well-being although this may be assumed to be part of the extension to life. In some cases this was viewed as a normal life expectancy but with a greater ability to make the best of what life could offer: *'I expect to live till between 70 and 80, hope to get a new capacity for life'* ; *'return to an expected standard of life'.*

The notion that the subjects themselves also had a role in influencing the outcome benefit was expressed: *'If you look after yourself, you will get another 20 years'*, *'if I stop smoking I will be a fit man again'.* In addition to extended life, the notion of restoration of health to an optimal level was raised in the expectations of some of the subjects for example, *'it will extend life expectancy and I'll be a new man'; 'it will make me feel 100%, be a lot fitter, be brand new'.* The term *'new man'* was mentioned by a number of male subjects but interestingly, the term *'new woman'* was not used by female subjects. This appeared to be an expression of the desire and expectation that surgery would provide a means of rejuvenation. A similar desire was expressed in other ways for example: *'I will feel like 10-20 years younger'.* The notion of regained youth was often spoken about at the same time as quality of life by some subjects and in the following comment several concepts of outcome benefit were included: *'I hope to be a new man and get rid of the pain, improve quality of life'.* The sense of being given a second chance was evident in some comments: *'just like starting from scratch again'* ; *'it will make me feel 100% again'* implying that their view of the outcome benefit from surgery would be to restore their health status to an optimal level which may or may not be a realistic aspiration. Subjects in their comments related to expectation of health benefit from surgery did draw a distinction between extension to life span and quality of life, which for some was expressed as: *'I will feel good about myself again'.* Quality of life improvement was an expectation of many of the subjects although the detailed meaning of this term was not explored. Some subjects related improved quality of life to improved functional status as a result of relief of symptoms: *'I hope to have a better quality of life, can only walk 50 yards, if no nitrate spray'* while other expressed a general desire for: *'a better quality of life'* and generally to *'feel better'.* It was apparent from

the range of ways that quality of life was expressed that it held a different meaning for different subjects.

5.15 Conclusions

The baseline data have provided a summary of the demographic and clinical characteristics of the study cohort. To address the research questions relating to the health status of subjects prior to CABG surgery, the inter-relationship between the range of variables measured and the health expectations of subjects the following key points summarise the findings.

- The proportion of males and females in the study (74.4% males and 25.6% females) was similar to that of all patients undergoing CABG surgery in GGHB area.

- The mean age for both males and females was significantly lower ($p<0.001$ (M), $p<0.005$ (F)) and subjects were from areas of lower socio-economic deprivation than all patients undergoing CABG surgery in GGHB ($p<0.001$).

- Subjects from lower socio-economic groups had lower levels of health, as measured by the SF-36 scale.

- Longer waiting times for CABG surgery were associated with lower levels of health as measured by the SF-36 scale.

- Symptoms of angina and breathlessness, as reported using a self-rated scale, were present in respectively 93.4% and 92.7% of the subjects.

- The level of angina and breathlessness symptoms on the self-rated scales were highly significantly correlated, $p<0.001$, which would suggest that the two symptoms are related and not independent of each other.

- Many of the main modifiable CHD risk factors were present in the study group; 22.9% were smokers; 80.8% had a BMI>25, 39% elevated systolic blood pressure,

30% elevated diastolic blood pressure and 67.4% had a cholesterol level of >5.2mmol/L. The majority of subjects had three or four modifiable CHD risk factors.

- Levels of health as measured by the SF-36 scale were low and statistically significantly lower than other patient groups with CHD.

- Health locus of control was similar to the MONICA population and the assessment of social network showed that the subject had similar scores to the published scale. A higher social network score was associated with improved health as measured by the SF-36 scale.

- * Subject reports on health and well-being focused on issues of dependency and the threat of a sudden major cardiac event or death occurring without warning.

- * Expectations of the benefit to health from CABG surgery were varied and uncertain and included the hope for freedom and independence, extended life expectancy and improved quality of life.

* These subjective accounts were part of a much richer qualitative picture that emerged in the study interviews and has been outlined in detail within results in chapter 5.

Chapter 6

6.1 Introduction

In this chapter the results are presented for the study cohort in respect of surgical outcome, re-assessment of baseline measurements, utilisation of cardiac rehabilitation and finally the subjects' views on their health as a result of CABG surgery and their experience of surgery. Comparisons have been made between phase I and phase II variables where there are matched pairs of data. For continuous variables the Student t-test was used, and for categorical variables the Wilcoxon and Chi-square tests were used.

6.1.1 Surgical Review

The CABG surgery records were assessed for the study subjects. From the clinical records, the following information was collected. The number of the original study subjects (n=215) who underwent CABG surgery was 209 (97.7%) with one patient undergoing valve surgery and not CABG surgery, having been incorrectly identified from the waiting list. Five patients (2.4%) did not have surgery because of an improvement in clinical status (n=1); surgical risk was re-evaluated and thought to be too high (n=1); subject choice (n=2); and no date for surgery had been allocated as it appeared that the records had been misplaced (n=1). This left 209 subjects of the original cohort to be evaluated during and after CABG surgery.

The number of vessels inserted during the CABG procedure for the study cohort (n=209) ranged from one to seven and are presented in figure 6.1. The procedure of anastomosing the internal mammary artery to the left anterior descending artery was conducted in 75.6% of subjects (n=158). The majority of both male and female subjects had three vessels inserted during surgery, an operation commonly referred to as ``triple bypass'' surgery.

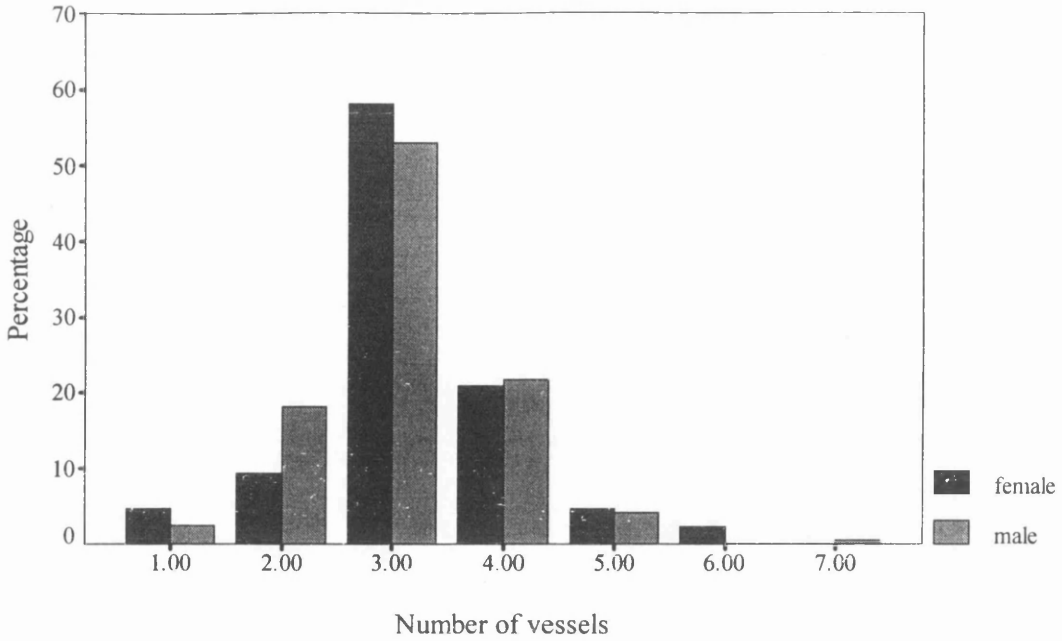

Figure 6-1. The number of vessels inserted at CABG surgery

6.1.2 Perioperative Mortality

Ten (4.8%) subjects (5 males and 5 females) died in the perioperative period as a result of complications during or following surgery. The perioperative mortality rate was significantly higher for females than males (p=0.019). Comparisons of the characteristics assessed in phase I of the study in those who survived and those who died were made. For females subjects there was no significant difference in baseline characteristics between those who died and those who survived surgery.

For male subjects the majority of baseline characteristics also showed no significant difference between those who died and those who survived surgery. However, those males who died had significantly lower SF-36 scores for social function (15.6 v 51.5, p=0.004), and mental health (38.4 v 63.5, p=0.001), significantly lower diastolic blood pressure (69.0 v 81.1mm Hg, p=0.035) and breathlessness self-rating (1.5 v 3.7, p=0.022) and a significantly higher average number of vessels inserted at surgery (4.0 v 3.1, p=0.012) than those males who survived.

For females and males there was no significant difference in their mean age (p=0.687), deprivation category (p=0.364), presence of diabetes mellitus, the number of risk

factors (as defined in table 5.5) and smoking status (p=0.824) between those who died and those who survived surgery.

Analysis of the effect of age and gender within the group that died was not possible because of the small numbers. The perioperative mortality rate was similar to that of other surgical centres as can be seen in table 2.3. In addition 19 (9.9%) of patients had extended time in hospital (greater than 14 days) due to complications.

6.1.3 Study subjects: Identification for follow-up

At the initial stage of the follow-up assessment for phase II of the study it was established that 199 (+ 6*) subjects had survived to a mean time point of 16.4 months following surgery. Through the tracing of patient records at the relevant health board, it was established that the subjects who were not known at their previous address were still alive according to their medical records. Follow-up to establish the survival status of the study subjects was 100% complete. Three subjects (two males; one female) died during the first year after surgery. Overall one year survival for those in the study cohort who had surgery (n=209) was 93.08 %.

It was not possible to complete the follow-up assessment for 13 subjects. This incomplete follow-up in phase II occurred because four subjects declined to take part at initial invitation, four subjects changed address without providing a forwarding address and five subjects, who initially agreed to participate and requested to be seen at the hospital clinic, subsequently defaulted. This resulted in a complete follow-up assessment of 183 + 6* subjects, representing 87.9% of the original cohort (n=215) that were recruited to the study.

* The five patients who had been removed from the surgical waiting list and the one patient who had valve surgery were also reviewed during phase II of the study although for analysis purposes these data were considered separately from that of the main study cohort.

6.1.4 Hospital re-admissions

There were 44 subjects re-admitted to hospital during the period from hospital discharge after CABG surgery to the phase II assessment. This represented 24.0% of

the study cohort (n=183). The primary diagnosis (provided by the subject) was chest pain (n=15), congestive cardiac failure (n=6), stroke (n=4), cardiac arrhythmia (n=7), pulmonary embolism (n=3), wound infection (n=3), faint/blackout (n=3), myocardial infarction (n=2), and blood transfusion (n=1).

6.2 Phase II Assessment Self-complete questionnaires

A total of 183 subjects completed follow-up assessment in phase II of the study which was undertaken at a mean of 16.4 months after surgery. The following data were collected using the self-complete questionnaires provided in Appendix IX.

6.2.1 Angina and Breathlessness Symptoms

The subjects were asked to report if they had experienced angina or breathlessness symptoms again on a regular basis in the time period since their surgery. If symptoms were experienced, the subjects were asked to rate the level of severity as before on a rating scale. Data were completed by 182 (99.5%) subjects at follow-up. Student's paired t-test was used to compare angina and breathlessness scores at phase I against those at phase II. A total of 54.9% reported no angina symptoms compared to 5.8% at phase I assessment. Of the 45.1% (n=82) of subjects who reported angina symptoms at phase II, their mean angina scores at phase II were highly significantly reduced (4.28 SD 1.67 vs. 2.75 SD 1.59, $p<0.001$). A total of 36.3% reported no breathlessness symptoms at phase II assessment compared to 7.9% at phase I assessment. Of the remaining 63.7% (n=116) who reported breathlessness symptoms at phase II, their mean breathlessness scores at phase II were significantly reduced (4.34 SD 1.67 vs. 3.52 SD 1.81, $p=0.001$).

The overall change in angina and breathlessness measured over all subjects (n=178) with paired data indicated that the self-rating scores in both of these symptoms were highly significantly reduced ($p<0.001$). Specifically the mean angina I and angina II scores were respectively 4.23 with SD 1.76 and 1.25 with SD 1.74 while the mean breathlessness I and breathlessness II scores were respectively 3.90 with SD 1.90 and 2.19 with SD 2.19.

6.2.2 Recall of pre-operative breathlessness symptom at follow-up

The subjects were asked to recall the level of angina and breathlessness symptoms experienced at phase I assessment on the same self-rating scale. These recall scores, provided at the follow-up visits, correlated well with scores provided pre-operatively are outlined in table 6-1. This would suggest that patients' interpretation of level of symptoms before their surgery could be recalled with some accuracy. This symptomatic assessment could be useful as a measure of clinical improvement after surgery in the absence of assessment of pre-operative symptom level.

Table 6-1. Comparison of recall of angina and breathlessness symptom ratings using paired t-test

symptom rating	mean (SD) phase I	mean (SD) phase II	p-value
angina (n=178)	4.23 (1.76)	4.46 (2.41)	0.274
breathlessness (n=178)	3.90 (1.90)	4.18 (2.42)	0.196

6.3 Cardiac Rehabilitation Attendance

Subjects were asked to indicate if they had attended a cardiac rehabilitation programme. The responses from the subjects showed that the majority had attended that is 119 (65.0%) with a small number of subjects 19 (10.4%) who attended for part of the programme (less than 50%) and approximately a quarter 44 (24.1%) subjects who did not attend a cardiac rehabilitation. One subject did not respond to the question. Reasons for non-attendance given were provided by 23 subjects (52.0%) and were as follows: Not invited (n=3), didn't like the programmes (n=2), couldn't do warm-up exercises (n=3), transport problems (n=4), ill-health (n=7), did exercises at home(n=3) and returned to work (n=1).

6.3.1 Attributes of cardiac rehabilitation

Cardiac rehabilitation programmes at different centres vary in terms of the date of commencement in relation to the time of surgery and the length and content of the course. Subjects in the study were invited to attend a cardiac rehabilitation

programme at varying times ranging from eight to 12 weeks after surgery. An invitation to attend cardiac rehabilitation was extended from the nearest centre and was not necessarily the hospital where the surgery was performed.

The responses to the questions asking subjects who participated in a cardiac rehabilitation programme to comment on their view of its positive and negative attributes, were analysed to identify themes according to previously described methodology (Morse and Field, 1996). A large number of the subjects who attended the programme did not answer the section which invited positive and negative comments to be made and others did not provide any more details than '*I liked all of it*'. The following analysis therefore is based on a subset of the study cohort.

6.3.2 Positive attributes

Many positive comments were made by subjects on the value of attending a cardiac rehabilitation programme. Some subjects reported that they enjoyed all parts of the programme but specific reference was made to the beneficial effects of the exercise component and to a lesser extent the lectures. It was clear from the comments that exercise was viewed as the central focus of the programme and was an area that most subjects referred to when recounting their experiences. Two themes were identified from the responses, namely, that of 'Common sharing' and 'Confidence building'

6.3.3 Common sharing

The importance of the other people involved in both the provision and participation of the cardiac rehabilitation programme was an important factor for many of the subjects. For one subject it was: '*the company of others, with the same problems..... still such a cheery bunch*' that was something he looked forward to each week. The contact with other patients and staff were mentioned in terms of :'*friendship*' and '*comradeship*', indicating the warmth and depth with which these relationships were viewed not just as casual passing acquaintances. Others reported similar thoughts: '*being with people in the same position as yourself*' - as an important dimension of the programme and should have implications for the expansion of home-based programmes which would miss out on this valued aspect of rehabilitation. The strength and encouragement drawn from the recovery of fellow patients was an

important incentive and promoter of their own well-being for some as highlighted in the following comment: *'it was better than all the medicines, as others progressed, so did you, it was good to meet people like myself'.*

6.3.4 Confidence building

The exercise component of cardiac rehabilitation continued to be the point of reference to which subjects assessed the programme. Through their gradual mobilisation and increased exercise capability, an insight into the feelings of lost confidence was provided. One subject commented that: *'the supervised exercises were morale boosting and particularly the relaxation exercises; it was a controlled environment; it was safe to push yourself'.* Another subject supported the value placed on supervision and the pacing of the exercises so that she could cope and gain reassurance that she was making progress in her comment: *'the gradual, guided build up of exercises was good, supervised exercise and peer support'.* Many subjects would have liked the programmes to continue as this response indicated: *'I was disappointed when it stopped, doing exercises I would never have contemplated before'.* The fact that the exercises were graded and supervised in a safe environment was an important positive factor for the majority of subjects, who felt that they could safely attempt exercises that they previously thought might cause harm. This aspect of safety was seen as a source of building confidence: *'given targets that gives you confidence to push yourself, everything catered for individual, enjoyed all of it, people and the staff made it worth while'.* A general feeling of high levels of satisfaction came through the majority of comments and is aptly captured in the following comment: *'loved exercises, made me feel 200% fit, hard work, but could feel the benefit at the end, enjoyed lectures and exercises'.*

6.3.5 Negative

The number of comments that highlighted negative aspects of cardiac rehabilitation were much less than the positive comments. Some male subjects made vague comments such as: *'don't like that sort of thing'* which on further enquiry they added that they did not like group activities or classes of any type and in particular for one subject reminded him of being at the school gym. A number of male subjects thought that there were too many women. Some female subjects thought that there

were too many men and generally others thought that there were either too many people or that they considered the others too old in comparison to themselves. It was difficult not to conclude that 'you can't please all of the people all of the time'. Two main themes were identified in the responses related to '*nature of the exercises*' and '*transport*' as areas that were considered as negative.

6.3.6 Nature of the Exercises

The most common negative comments were in relation to the exercise component of cardiac rehabilitation programmes. This was in part due to the subjects reporting that they were unable to keep to time with the exercises. As one women pointed out: *'the warm up was too fast for my poor synchronisation; I had difficulty in co-ordinating myself with the instructor'*. Others said that they had a problem '*balancing*', and for many this was the first time they had undertaken any formal type of exercise since they had been at school over 30 years ago. Exercises that involved stepping, bending or press-ups were not welcomed by many of those subjects who found that they were too hard or difficult. A few subjects thought that the type of exercises were just not something that they would enjoy, describing them as '*silly exercises*'. Others commented that the exercises were *'too vigorous'*. A number of subjects reported that they: *'didn't feel physically up to it'*, which may be because the exercises were in fact too demanding or that they needed more time to recover from the surgery. A series of comments that related to the subjects health status were made in relation to their viewing cardiac rehabilitation as a negative experience at that time or a reason for failing to attend: '*unfit to attend*', *'couldn't breath'*, *'trouble with throat'*, *'couldn't lie flat'*. One women was unhappy with the exercises because: '*I was given someone to look after and couldn't cope'*, a situation that may have arisen because there were often less women than men and generally new attendees were introduced to other patients who had been attending for some time to provide some informal support and company.

6.3.7 Transport

Several subjects were reliant on either public transport or the ambulance service for transport to the classes and this was viewed as less than ideal by some subjects in terms of the arrangements and time delays, as one subject commented: '*there was a*

lot of fuss waiting for transport'. These were seen by a number of the subjects to outweigh benefits of attendance at the rehabilitation classes. The delays that had occurred in picking up subjects also had an effect on others participating in the programme: *'there were delays in getting transport to the hospital...this meant classes were delayed or disrupted'*. This problem had been addressed in other areas through the establishment of community-based classes. Although, a minority group, some subjects said that they preferred to do their exercises at home and gave this as their reason for discontinuing the programme.

6.3.8 Angina and breathlessness symptoms and attendance at cardiac rehabilitation

The presence or absence of angina and breathlessness symptoms between subjects who fully attended, partially attended or did not attend a cardiac rehabilitation programme was tested. There was no statistically significant difference between any of the groups ($p>0.138$). Similarly, in subjects who had symptoms there was no difference in attendance pattern in relation to the severity of the symptoms ($p>0.138$).

6.3.9 Cardiac rehabilitation and CHD risk factor status

The presence of CHD risk factors in each of the subject groups as defined by attendance at a cardiac rehabilitation programme (complete, partial or non-attendance) were compared (Mann-Whitney U test). The results showed that there was no significant difference in the number of CHD risk factors above target levels between full attendees and non-attendees ($p=0.25$) or between full attendees and partial attendees ($p=0.17$) or non-attendees and partial attendees ($p=0.18$). The relationship of attendance at cardiac rehabilitation and health status as measured by the SF-36 questionnaire are presented in section 6.7.3. The extent to which CHD risk factors remain uncorrected is presented in section 6.4.3.

6.4 Clinical Assessment Phase II

The clinical assessment was undertaken according to the protocol in Appendix X and included the same measurements as at baseline assessment. The mean values and standard deviations for diastolic and systolic blood pressure, plasma cholesterol level, BMI, waist circumference, smoking status and presence of diabetes mellitus

are presented in table 6-2. Various tests were used to compare these variables between the male and female subjects and showed that there were no statistically significant differences in systolic blood pressure, diastolic blood pressure (t-test), presence of diabetes mellitus (Chi-squared test) or smoking status (Chi-squared test). However, plasma cholesterol levels and BMI scores were statistically significantly (t-test) higher in females than males.

Table 6-2. Mean values for major CHD risk factors for study cohort and by gender at phase II assessment. (discrete variables compared with Chi-squared test and continuous variables with t-test).

CHD risk factor	Total (n=172) mean (SD)	males (n=140) mean (SD)	females (n=32) mean (SD)	p-value
#DBP II (mm Hg)	86.8 (13.1)	86.7 (12.6)	87.3 (15.7)	0.811
#SBP II (mm Hg)	147.7 (24.9)	145.6 (25.2)	154.4 (24.3)	0.092
#Tchol II (mmol/l)	5.42 (1.16)	5.31 (1.12)	5.93 (1.23)	**0.007**
*BMI-II (kg/m)	28.19 (3.54)	27.92 (3.64)	29.43 (2.79)	**0.026**
*waist II (cm)	96.84 (8.59)	97.71 (8.50)	92.86 (7.97)	**0.003**
*diabetes mellitus	12.7%	11.5%	17.9%	0.280
*current smoking II	24.9%	23.8%	29.4%	0.415

Statistically significant p values in bold.

*(n= 182, males n=150, females n=32) # (n= 172, males n=140, females n=32)

6.4.1 Comparison of phase I and phase II CHD risk factors

Paired samples t-tests were used to establish if the mean diastolic and systolic blood pressures, plasma cholesterol level, waist circumference and BMI measurements had changed significantly between phases I and II.

Table 6-3. Comparison of percentages of subjects with major CHD risk factors above target levels between phase I and phase II assessment
(Wilcoxon matched pairs signed rank test)

action level	Phase I	Phase II	p-value
SBP > 140 mm Hg, n=169	39.0	60.5	**<0.001**
SBP > 160 mm Hg n=169	11.9	37.2	**<0.001**
DBP > 90 mm Hg n=169	30.0	43.6	**<0.001**
DBP >100 mm Hg n=169	9.0	21.1	0.130
Tchol > 5.2mmol/l n=149	67.4	56.1	**0.005**
BMI>25kg/m^2 n=184	80.8	81.0	0.379
BMI>30kg/m^2 n=184	22.9	27.2	0.382
waist> (80cm/f 94cm/m)	69.2	72.8	0.379
waist> (88cm/f 102cm/m)	36.9	41.3	0.382
diabetes mellitus	12.6	12.7	0.213
current smoking n=185	22.9	24.9	0.493

Statistically significant p values in bold font.

The presence of CHD risk factors above target levels were examined in males and females were separately and statistically significant changes are presented in table 6-3. For males, no significant improvements were noted in the BMI score or waist circumference. However, diastolic and systolic blood pressures were highly significantly increased and plasma cholesterol levels highly significantly decreased at phase II assessment as presented in table 6-4.

Table 6-4. CHD risk factors in males that have changed significantly between phase I and phase II assessment.

CHD risk Factor	number males	phase I mean (SD)	phase II mean (SD)	p-value
SBP II (mm Hg)	139	132.7 (20.4)	145.8 (25.1)	**<0.001**
DBP II (mm Hg)	139	80.9 (12.6)	86.8 (12.6)	**<0.001**
Tchol II (mmol/l)	123	5.66 (1.04)	5.28 (1.11)	**<0.001**

Statistically significant p values in bold font.

Paired data existed on 30 female subjects and were used as the basis of a paired samples t-test to establish if mean blood pressures, plasma cholesterol level, BMI score and waist measurement changed significantly between phases I and II. A statistically significant increase in mean systolic blood pressure from 140.4 mmHg with SD 23.2 to 155.9mmHg with SD 24.2 (p=0.009) was the only change noted. The Wilcoxon matched pairs signed rank test was applied to the smoking status for both males and females and indicated that at phase I and phase II assessments the smoking status was not significantly different.

6.4.2 Presence of CHD risk factors above target levels

The main modifiable CHD risk factors (diastolic and systolic blood pressures, BMI scores, plasma cholesterol levels and waist circumference) that were assessed at phase I, according to the recommended guideline levels outlined in table 5-5, were re- assessed using the same criteria at phase II and the results presented in table 6-5. As can be seen from table 6-5, a large percentage of male and female subjects had CHD risk factors above target levels. There were no statistically significant differences in the percentage of male and female subjects above target levels for systolic and diastolic blood pressures, current smoking status or diabetes mellitus. However, statistically significantly higher percentages of female subjects had plasma cholesterol levels (p=0.037), BMI scores (p=0.030) and waist circumferences (p=0.001) above target levels than was the case for males.

Table 6-5. Percentage of study cohort with CHD risk factors above guideline targets for males and females at phase II

action levels	total (percent)	Male (percent)	female (percent)	p-value
SBP > 140mm Hg	60.5	58.6	68.7	0.289
SBP > 160mm Hg	37.2	35.7	43.8	0.398
DBP > 90mm Hg	43.6	45.7	34.4	0.245
DBP > 100mm Hg	21.1	20.0	31.3	0.168
Tchol > 5.2mmol/l	56.1	48.9	73.3	**0.037**
BMI>25kgm	81.0	78.1	93.9	**0.037**
BMI>30kgm	27.2	23.8	42.4	**0.030**
waist> (80cm/f 94cm/m)	72.8	67.5	97.0	**<0.001**
waist> (88cm/f 102cm/m)	41.3	33.1	78.8	**<0.001**
diabetes mellitus	12.7	11.5	17.9	0.280
current smoking	24.9	23.8	29.4	0.415

Statistically significant p values in bold font.

6.4.3 The presence of multiple CHD risk factors

The presence of multiple CHD risk factors was assessed in the study cohort as defined by the guideline criteria outlined in table 6.5. and are presented in table 6.6. As can be seen from table 6-6 and figure 6-2, the majority of subjects in the group as a whole had multiple risk factors and that approximately two-thirds had three or four risk factors.

Table 6-6. Number of CHD risk factors present in study subjects at phase II assessment

sample	no risk factors	1 risk factor	2 risk factors	3 risk factors	4 risk factors	5 risk factors
study (n=158)	3.2%	8.9%	19.0%	31.6%	29.7%	7.6%
(cumulative)	(3.2%)	(12.1%)	(31.1%)	(62.7%)	(92.4%)	(100%)
male (n=130)	3.8%	10.8%	20.0%	33.0%	26.2%	6.2%
(cumulative)	(3.8%)	(14.6%)	(34.6%)	(67.6%)	(93.8%)	(100%)
female (n=28)	0.0%	0.0%	14.3%	25.0%	46.4%	14.3%
(cumulative)	(0.0%)	(0.0%)	(14.3%)	(39.3%)	(85.7%)	(100%)

Note: Subject numbers are presented only when data were available for all CHD risk factors

The Wilcoxon test was applied to test differences in the numbers of risk factors for males and females and indicated that males and females have profiles of risk factor clustering that is very significantly different (p=0.003). This test does not allow comparisons to be made between the individual sub-groups with specific numbers of risk factors.

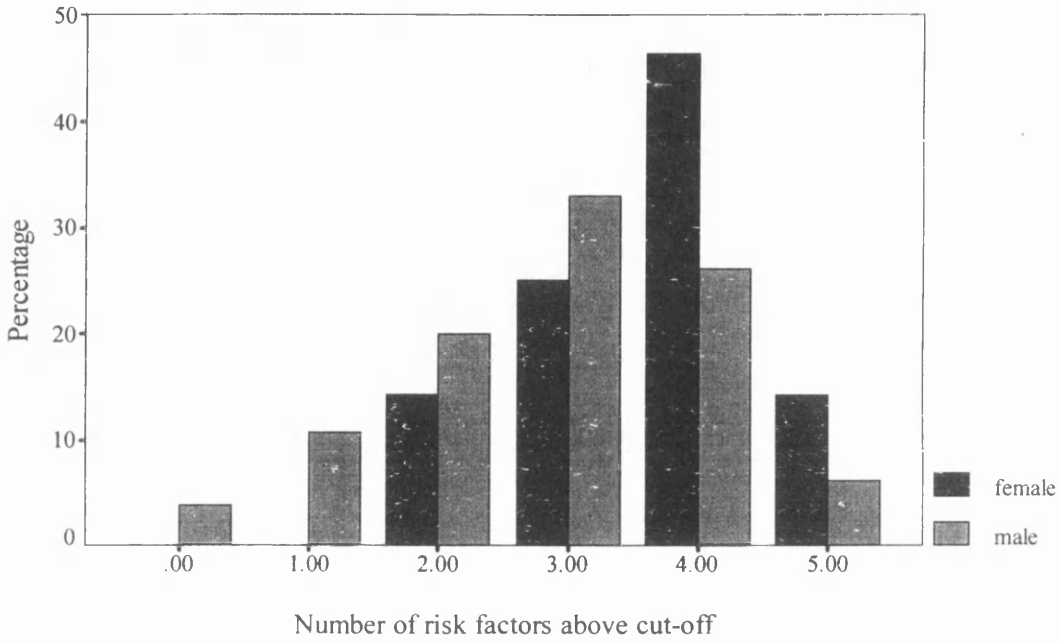

Figure 6-2. Number of CHD risk factors above target levels for males and females at phase II

6.5 Social network scores

Social network scores were calculated at phase II from the questionnaires returned by 133 (72.7%) subjects comprising 16 females and 117 males. The profile of scores is displayed in figure 6-3 and shows a range of values from 8 to 44. The mean score for the total cohort was 24.1 with SD 7.2 (n=133) while the mean score for females was 25.3 with SD 10.3 (n=16) and for males the mean score was 24.0 with SD 6.7 (n=113). An independent samples t-test indicated no significant difference between male and female phase II social network scores (p=0.511). The higher the score the stronger the social support.

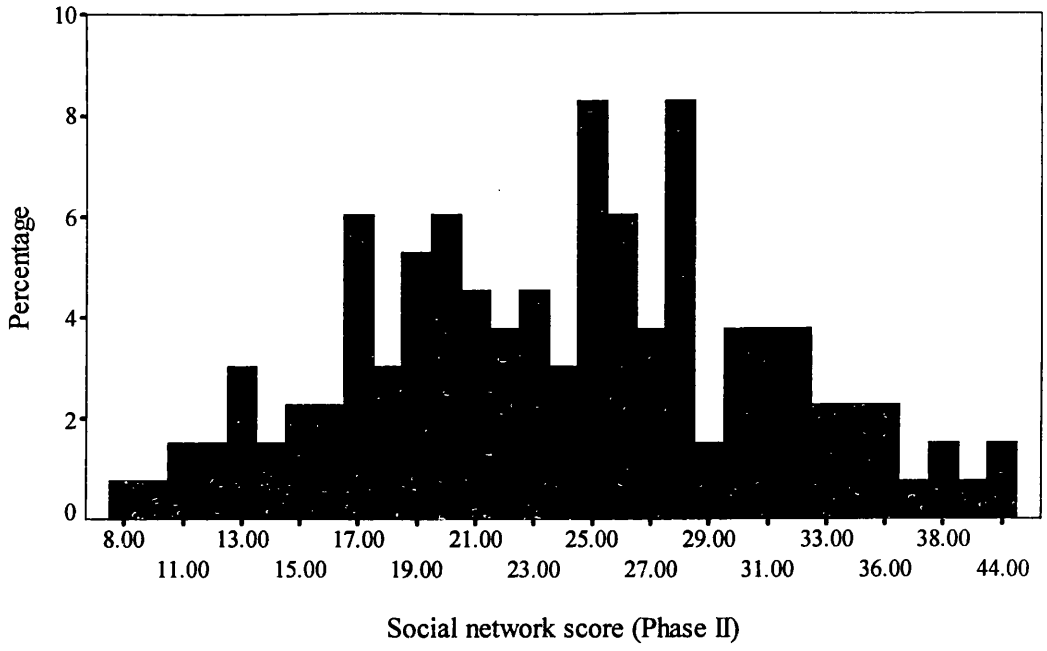

Figure 6-3. Social network score at phase II assessment

A paired samples t-test was used to compare the mean social network score at phases I and II. For 126 paired-samples, the phase I mean was 24.6 with SD 6.5 and the phase II mean was 24.3 with SD 7.1. No significant difference (p=0.498) was detected between the mean social network scores at phases I and II. The mean phase II social network score in this study was compared to that of the population group who participated in the health insurance experiment (HIE) (mean=25.8, SD=7.97) (Donald and Ware, 1982). An unpaired Student's t-test indicated that the mean score in this study was very significantly less than that of the HIE (p=0.004).

6.6 Health Locus of control

The HLOC scores obtained at Phase II assessment were calculated from the responses of 97 (53%) subjects who answered the section of the self report questionnaire pertaining to HLOC. Total scores ranged from values of 19 to 37 with a mean of score of 28.4 and SD 3.9. The mean for female subjects (n=10) was 26.1 with SD 3.5 and for male subjects (n=87), the mean score was 28.6 with SD 3.9. A paired samples t-test indicated that the phase II means for males and females were significantly different (p=0.05). Figure 6-4 shows the distribution of HLOC II, the phase II HLOC scores.

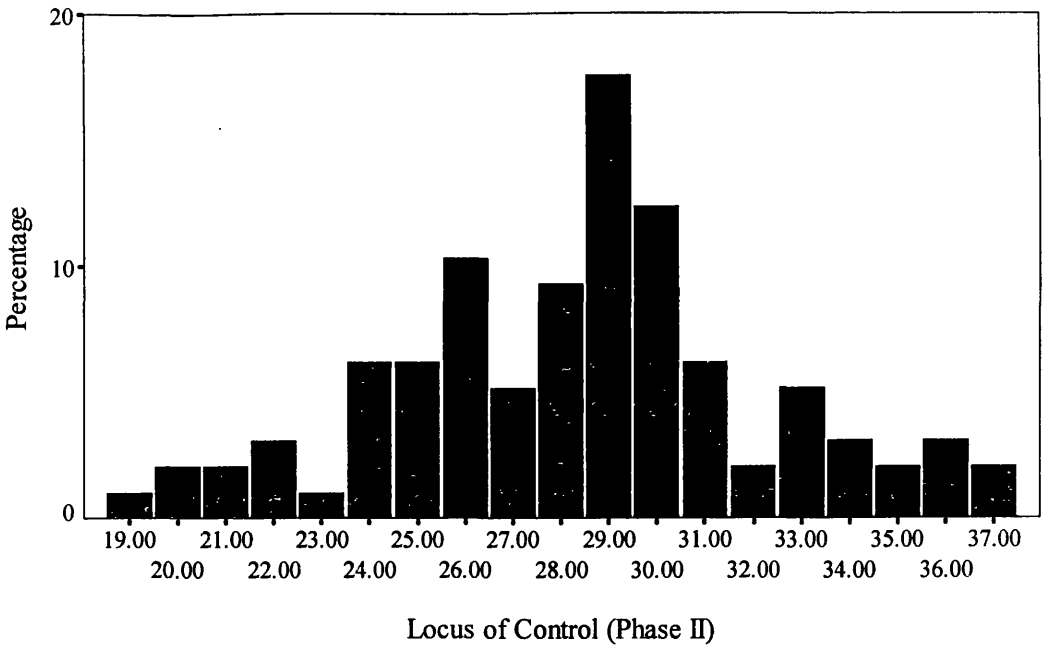

Figure 6-4. Health locus of control scores at phase II assessment

6.7 SF-36 Health Assessment

The SF-36-II questionnaires were completed by the majority of the subjects (n=180, 98.4%) and mean scores are presented with the main summary statistics in Appendix XIV. For each SF-36-II domain, subjects' scores range from 0 to 100 except for general health where the range was from 5 to 100 and mental health where the range was from 24 to 100.

6.7.1 Changes in SF-36 scores between phase I and phase II

A paired Student's t-test was used to compare mean SF-36-II and SF-36-I scores for each domain. Because there was a smaller number of subjects at phase II it was not possible to have complete paired data. The number of subjects with paired data is included in table 6-7 together with the comparison of means.

Table 6-7. Comparison of SF-36-I and SF-36-II scores

SF-36 domains	mean (SD) phase I	mean (SD) phase II	number pairs	p-value
Bodily pain	45.2 (25.6)	61.2 (28.9)	170	**<0.001**
Energy/vitality	37.1 (20.6)	47.9 (23.5)	169	**<0.001**
General health	37.1 (17.2)	54.7 (24.2)	171	**<0.001**
Mental health	61.1 (18.6)	65.6 (18.5)	169	**0.006**
Physical function	36.3 (24.0)	57.4 (29.2)	171	**<0.001**
Role: emotional	38.0 (43.7)	51.4 (46.3)	162	**0.001**
Role: physical	15.4 (31.9)	40.9 (45.5)	167	**<0.001**
Social function	50.4 (27.5)	68.5 (29.9)	170	**<0.001**

Statistically significant p values in bold font.

The minor differences in the mean and SD between the SF-36-II scores in Appendix XIV and those in the table 6-7 arise because a paired t-test required subjects to have scores from phases I and II. The summary statistics calculated for the phase II scores were based on all subjects who completed the SF-36 questionnaire at follow-up (n=180) irrespective of whether a SF-36-I questionnaire had been completed. The mean SF-36 scores are statistically very significantly increased between phases I and II.

A comparison of SF-36-II scores with that of a United States healthy population (Ware Jr et al, 1993) are presented in table 6-8 and show that the scores in the study subjects after CABG are still statistically, highly significantly lower, than those of a healthy population. The SF-36 scores for the study subjects have also been compared to a UK population (male) (Jenkinson, Coulter and Wright, 1993) and the results presented by age bands in table 6-9. The results for males and females were presented separately and for comparative purposes, because the majority (>80%) of the study subjects were male, a comparison has been undertaken with the study subjects and the male population results. This was not an ideal comparison group

both because it is for males only and the age range was from 18-64 years representing a younger population than the study subjects. Again the subjects in the study after CABG surgery have highly statistically significantly lower scores than the UK health population.

Table 6-8. Comparison of mean SF-36-II scores (SD) with those of a US healthy population (Mann-Whitney U test)

SF-36 II domains	mean scores (SD) healthy (n=2474)	subjects	n	p-value
Bodily pain	75.2 (23.7)	44.1 (25.9)	178	**<0.001**
Energy/vitality	60.9 (22.7)	48.3 (23.4)	179	**<0.001**
General health	72.0 (20.4)	54.7 (24.0)	180	**<0.001**
Mental health	74.7 (18.1)	66.1 (18.4)	179	**<0.001**
Physical function	84.2 (23.3)	54.0 (29.2)	180	**<0.001**
Role: emotional	81.3 (33.0)	51.6 (46.3)	170	**<0.001**
Role: physical	81.0 (34.0)	40.9 (45.4)	176	**<0.001**
Social function	83.3 (22.7)	68.9 (29.6)	179	**<0.001**

Statistically significant p values in bold font.

Table 6-9. Comparison of mean SF-36-II scores (SD) for study subjects* with those of a UK healthy population (male) # by age bands (Mann-Whitney U test).

SF-36 II Domains	Ages (35-44yrs) n=1000# / n=10*	Ages (45-54yrs) n=840# / n=47*	Ages (55-64yrs) n=709# / n=91*
Bodily Pain	85.6 (19.7) / 34.7 (23.5)	81.8 (22.2) / 64.5 (28.3)	78.8 (23.6) / 62.6 (29.0)
Energy Vitality	63.5 (18.6) / 28.0 (18.4)	62.9 (19.9) / 49.9 (22.5)	62.9 (20.3) / 47.5 (23.6)
General Health	74.1 (18.5) / 28.9 (25.0)	72.0 (21.1) / 55.9 (21.4)	68.1 (22.9) / 55.1 (24.6)
Mental Health	75.0 (16.1) / 58.0 (19.6)	76.0 (16.7) / 64.8 (19.2)	78.0 (17.3) / 66.3 (18.5)
Physical Function	91.9 (14.5) / 31.6 (23.0)	87.9 (17.4) / 65.0 (29.0)	80.0 (22.1) / 55.3 (28.6)
Role: Emotional	86.0 (28.6) / 37.0 (48.4)	85.7 (29.5) / 58.2 (45.3)	85.8 (29.9) / 49.6 (46.5)
Role: Physical	89.5 (25.5) / 10.0 (31.6)	87.6 (28.3) / 52.2 (47.4)	78.8 (36.1) / 36.5 (43.2)
Social Function	90.5 (17.0) / 38.7 (23.8)	89.8 (18.7) / 74.7 (26.1)	86.9 (22.6) / 66.3 (31.4)

(All differences were highly significantly lower in the study subjects, $p<0.001$)

6.7.2 Trend of changes in SF-36 scores

The percentage and mean changes in the direction of the SF-36 scores between phases I and II have been calculated and are presented in table 6.10.

Table 6-10. Number of subjects (percentage) with decreased, no change and increased SF-36 domain scores (mean) between phase I and phase II

SF-36-II domains	pairs	no. (%) decrease (mean)	no.(%) no. change	no. (%) increase (mean)
Bodily Pain	170	46 (27.1%) (-20.5)	19 (11.2%)	105 (61.8%) (34.9)
Energy Vitality	169	45 (26.6%) (-18.0)	12 (7.1%)	112 (66.7%) (23.6)
General Health	171	40 (23.4%) (-15.2)	4 (2.3%)	127 (74.3%) (20.1)
Mental Health	169	62 (36.7%) (-16.1)	12 (7.1%)	95 (56.2%) (18.6)
Physical Function	171	41 (24.0%) (-19.0)	4 (2.3%)	126 (73.7%) (34.8)
Role: Emotional	162	29 (17.9%) (-63.8)	76 (46.9%)	57 (35.2%) (70.8)
Role: Physical	167	13 (7.8%) (-51.9)	86 (51.5%)	68 (40.7%) (72.4)
Social Function	170	39 (22.9%) (-24.3)	16 (9.4%)	115 (67.6%) (35.0)

The majority of the SF-36 scores either improved or deteriorated except for physical and emotional role limitation where approximately half of the cohort showed no change in their score. There were large improvements in all SF-36-II domains ranging from approximately 35% in physical role limitation to over 70% in physical function. However, for all the SF-36-II domains except physical role limitation, approximately 20% to 36% of the cohort (dependent on the domain) decreased their scores, indicating a deterioration in their health status for that domain.

6.7.3 Cardiac rehabilitation and health status (SF-36 II)

The SF-36 II scores obtained from those subjects who attended and completed a cardiac rehabilitation programme were compared using a Student's t-test and the results presented in table 6-11. Subjects who attended had improved health status as measured by the SF-36 scale across all eight health domains. These improvements

were highly significantly better in the general health domain and significantly higher in the physical function, physical role limitation and social function domains for attendees compared to non-attendees.

Table 6-11. Comparison (unpaired t-test) of SF-36-II scores between non-attendees and full attendees of cardiac rehabilitation programme

SF-36-II domains	mean (SD) attendee (n=114)	mean (SD) non-attendee (n=41)	p-value
Bodily pain	64.9 (28.1)	61.0 (28.2)	0.443
Energy/vitality	50.9 (24.0)	43.1 (21.3)	0.067
General health	59.9 (23.8)	45.6 (21.8)	**0.001**
Mental health	68.1 (18.7)	64.4 (17.4)	0.266
Physical function	63.7 (27.4)	50.7 (28.0)	**0.010**
Role: emotional	56.4 (46.0)	45.8 (45.1)	0.215
Role: physical	48.4 (45.9)	29.3 (41.0)	**0.020**
Social function	74.0 (26.9)	62.2 (32.4)	**0.040**

Statistically significant p values in bold font.

The SF-36 II scores obtained from those subjects who partially attended (less than half of the programme) and did not attend a cardiac rehabilitation programme were compared using a Student's t-test and the results presented in table 6-12. There were no significant differences between either groups in health status as measured by the SF-36 scales across all eight health domains.

Table 6-12. Comparison (unpaired t-test) of SF-36-II scores between non-attendees and partial attendees of cardiac rehabilitation programme

SF-36-II domains	mean (SD) partial attendee (n=18)	mean (SD) non-attendee(n=41)	p-value
Bodily pain	47.5 (29.2)	61.0 (28.2)	0.101
Energy/vitality	48.2 (24.1)	43.1 (21.3)	0.414
General health	48.2 (23.0)	45.6 (21.8)	0.678
Mental health	59.8 (18.7)	64.4 (17.4)	0.372
Physical function	39.8 (30.4)	50.7 (28.0)	0.185
Role: emotional	45.8 (50.0)	45.8 (45.1)	1.000
Role: physical	33.8 (47.6)	29.3 (41.0)	0.715
Social function	63.1 (31.1)	62.2 (32.4)	0.921

Statistically significant p values in bold font.

A comparison was then undertaken between SF-36 II scores for full attendees and partial attendees at cardiac rehabilitation and the results are presented in table 6-13. There was a highly significant improvement in physical function and a significant improvement in bodily pain for attendees compared to partial attendees. However, the majority of the health domains were not different between the two groups.

Table 6-13. Comparison (unpaired t-test) of SF-36-II scores between attendees and partial attendees of cardiac rehabilitation programme

SF-36-II domains	mean (SD) partial attendee (n=18)	mean (SD) attendee (n=114)	p-value
Bodily pain	47.5 (29.2)	64.9 (28.1)	**0.017**
Energy/vitality	48.2 (24.1)	50.9 (24.0)	0.662
General health	48.2 (23.0)	59.9 (23.8)	0.053
Mental health	59.8 (18.7)	68.1 (18.7)	0.084
Physical function	39.8 (30.4)	63.7 (27.4)	**0.001**
Role: emotional	45.8 (50.0)	56.4 (46.0)	0.399
Role: physical	33.8 (47.6)	48.4 (45.9)	0.226
Social function	63.1 (31.1)	74.0 (26.9)	0.131

Statistically significant p values in bold font.

6.7.4 Correlation SF-36-II scores and other phase II variables

Bivariate correlations were computed between each SF-36-II domain and the subject variables outlined in Appendix XII and are presented in the tables A and B in Appendix XVII. The figures in brackets denote the numbers of datum on which each partial correlation was based. To improve readability, each statistically significant correlation is bold.

The findings in correlation tables A and B in Appendix XVII illustrate general trends rather than powerful indicators of the interdependence of SF-36-II scores on other phase II variables. They indicate that angina II and breathlessness II have the strongest correlation with the SF-36-II domains. Angina II (yes/no), breathlessness II (yes/no), angina II (+ve) and breathlessness II (+ve) each exhibit statistically significant negative correlations (many highly significant) with all the SF-36-II domains except emotional role limitation in the case of angina II (+ve). Based on analysis including 178 subjects, 29.4% of angina II scores and 38.8% of breathlessness II scores can be explained by the linear regressions:-

(angina II)=3.603-0.021(SF-36-II BP)-0.019(SF-36-II GH)

(b*reathlessness* II)=5.423-0.028*(SF-36-II PF)-0.028(SF-36-II GH)

The coefficients in both these regressions are all statistically highly significant. In fact, bodily pain dominates the behaviour of angina II while physical function dominates the behaviour of breathlessness II.

The second strongest correlations arise from SOC II, the phase II social networks score. Statistically significant positive correlations were detected between all the SF-36-II domains and SOC II with the exception of emotional role limitation. Therefore subjects with high social network scores tend to do better in virtually all the SF-36-II domains (except emotional role limitation).

All correlations between deprivation category and the SF-36-II domains were negative and statistically significant for five of the eight domains. Similarly, age-at-onset was positively correlated with all eight SF-36-II scores and age itself was positively correlated with all SF-36-II domains except physical function, the correlations with energy/vitality and general health being statistically significant in both cases.

All the SF-36-II domains were negatively correlated with current and past smoking status and with alcohol consumption. Only the correlations of energy/vitality, emotional role limitation and physical role limitation with current smoking II, the correlation of emotional role limitation with past smoking II and the correlations of energy/vitality, general health and mental health with alcohol are statistically significant in this study. Similarly, all the SF-36-II domains are negatively correlated with risk II (number of risk factors possessed by subjects at phase II), diabetes mellitus and HLOC II. The correlations of energy/vitality and emotional role limitation with risk II are statistically significant while four SF-36-II and six SF-36-II domains respectively are statistically significantly correlated with diabetes mellitus and HLOC II. However, the correlation coefficients for HLOC were, on average, lower that those for the social networks score and indicates that health locus of control is a less important predictor of SF-36-II scores than social network score.

The predominance of one type of correlation (+ve or -ve) against the range of SF-36-II domains suggests that, with more data, these correlations might move from the current level of statistical insignificance to one of statistical significance. The correlations between plasma cholesterol level II and the SF-36-II domains and between BMI-II and the SF-36-II domains both fall into this category. Each SF-36-II domain is negatively correlated with plasma cholesterol level II and BMI-II but none of the correlations are statistically significant in this study.

Finally, the correlations between the SF-36-II domains and diastolic and systolic blood pressure are all small and of variable positive and negative sign suggesting that these variables have little impact on SF-36-II domain scores.

6.8 Structured Interview

6.8.1 Introduction

The structured interview was conducted following clinical assessments had been made and the self-complete questionnaires were collected and checked for completeness and focused on the subjects' experience of undergoing CABG surgery and how they perceived that surgery had affected their health.

The study subjects were eager to talk about their experience and the impact that surgery had on their health and life in general. It appeared that considerable thought had been given to the whole experience of undergoing CABG surgery and the subsequent effects the surgery conferred to their health and well-being. Some subjects were generally satisfied with surgery even when they still had chest pain from time to time, for example : 'I *never expected to be perfect, glad to get it over with'* while others were totally happy with the result: *'I think the operation is perfect, did not know what to expect, no down side'.* A small minority of study subjects reported that they felt worse than before and were disappointed having had high expectations: *'I heard so much about other people being great'.* In particular, health problems identified as more of an issue than before surgery were reported as: *'more absent minded'* ; *'more exhausted and breathless'* in subjects who did not feel that the operation had been a complete success.

6.9 Benefit to health and well-being

A range of comments was provided in response to enquiry about their health status following surgery. Many of the comments on health status post-surgery were based on the same areas of concern as had been raised at the pre-surgical interview. From analysis of these comments two broad themes were identified namely; '*removal of a death sentence'* and '*freedom of choice'*.

6.9.1 Removal of a Death Sentence

Many subjects evaluated the benefit of having the surgery as a preventive strategy so that their future health would be secure: '*there is less risk of a heart attack now'; 'the fear of another heart attack goes*' were frequent comments. Such comments addressed and hopefully ameliorated the pre-operative concern of: 'impending doom' that had been a theme in the pre-operative accounts of health status. The removal of the threat of a catastrophic event occurring, with little notice but dire consequences was an important factor for many: *'I no longer sit waiting and worrying that something might happen to heart'*, with the notion that in addition to the relief of chest pain that their heart was now in some way safe from another critical event. This safety was expressed by others as '*being mended'* illustrating that surgery was in some ways offering a cure. Others expressed, in an even more basic way, the ultimate benefit of the surgery: '*If I hadn't had op, I would not be here today'*, they considered that the surgery had saved their life.

The threat of dying as a result of their heart condition was made more acute during the waiting time for surgery: '*I thought I might die, my condition was getting worse'*, as some subjects were aware that there was a noticeable deterioration in their health during that time. The life death dichotomy that was being described was also apparent in other comments: '*the operation has made me feel as if I have been reborn'* so for some the operation was viewed as an reprieve from death while for others it was to be given a life again.

6.9.2 Freedom of Choice

The influence of surgery on health was perceived by many in terms of the freedom to be able to undertake activities that they wanted to do: '*it is so nice to be able to do*

everyday things without thinking about it' without the need for forward planning that had been necessary before surgery. This release from the need for forward planning extended to being able to make commitments to people or events that they felt that they could now fulfil: '*know that if I say I am going somewhere, can go'* which was a very important issue for many of the subjects. Some of the areas of previous dependency were no longer a problem for example where in the past climatic conditions were critical to whether a person could be outdoors, this was no longer a barrier: '*can go out in the cold and wet weather now'*; *'can walk without stopping every twenty yards'.* The importance of removal or reduction in the limiting symptoms of angina and breathlessness and the consequent improvement in their basic mobility was highlighted by many study subjects.

6.10 Experience of surgery

There were a range of comments relating to the general experience of undergoing CABG surgery although the majority of subjects provided more comments about the effect of surgery on their health rather than the experience itself. The notion of being viewed as not fully fit and being viewed as in need of the support of others was raised: *'stigma having had operation, people take over think you cant cope'* with another subject reporting that: *'people were overprotective about what I could do'.* The helping efforts of others or the manner in which help or support was offered was not always welcome. Two main themes were identified in the accounts of the surgical experience were that of '*the importance of lay support'* and '*the enormity of the experience'.*

6.10.1 Enormity of the Experience

It is frequently reported in the lay press and media when a well known person has undergone CABG surgery in a positive and non-threatening way so that most subjects were familiar with the existence of such an operation and perhaps had a glamorous view of the whole process. However, many subjects found that it was a much more traumatising experience than they had been prepared for: '*it knocked hell out of me', 'I did not find it as easy as I had expected' ; 'I couldn't believe the pain*'. It was described in terms of a near death experience by some with one subject commenting: '*I thought at one time I wouldn't live through it,'* and another subject saying: *'I felt*

very vulnerable, hadn't thought about dying' with the surgery experience causing some subjects, first time, to reflect on the reality of their own mortality. The experience of surgery took a considerable time for many to recover from with comments such as: *'I cried for days when I got home';* alluding to the ongoing emotional effects in the immediate period after leaving hospital. Other subjects indicated that for them the return to what they considered normality was an extended period: *'it took me over nine months to feel myself again'.* In general, the reports indicated that the surgery experience was a greater challenge that they had expected, the pain was more severe, that they were weaker for longer and that the recovery process was variable but long.

6.10.2 Lay support

Subjects reported the importance of the contact with other patients and the subsequent friendships that were quickly established. The hospital ward had six bedded rooms where the majority of the subjects lived and slept during this time of recovery. One man reported that :*'it was like being in the trenches, we all looked out for each other , when we saw that someone was a bit down, we would try to cheer him up'.* The mood state was assessed by the subjects and other patients and appeared to be used as an indicator of well-being or the need for support. Although the average length of stay in hospital for surgery, with no major complications, was seven days, many subjects reported that friendships were made during that short time: *'I made friends in hospital and that helped so much....we still keep in touch; used to phone each other to see how things were going'.* In this case and for many others these contacts were maintained for the duration of the time between surgery and the follow-up assessment and continued to be a source of both information and support. It raises the potential problem of moving patients into different ward areas which could destroy the supportive relationships established between patients when there may not be clinically justifiable grounds for doing so. It was interesting to note that lay support was featured as such a source of help and support and not nursing or medical staff. This may be because it was an unexpected finding for the subjects and that support from healthcare professionals was expected. The notion of being given the impetus and strength to struggle against adversity was raised by a number of subjects and highlighted simply in one comment: *'other patients kept me going, we*

are all on the same boat'. The fact that other people were going through the same experience set them apart from other sources of help and support and was noted by a number of subjects to be a very strong means of comfort. In general terms, the fact that so many other people have had the CABG surgery and had made a good recovery was used as a means of reassurance that they would similarly do so: *'heard so much about others being great, the number of people who have had the operation is reassuring'*. In particular, the mobilisation and recovery patterns of patients who were nearing discharge provided the a reality of recovery was possible: *'we couldn't believe that he was able to walk right down the corridor.... he couldn't lift his head the other day'* and in a short time and provided an incentive to mobilise and deal with the recovery process.

6.11 Conclusions

In addressing the research questions of the health status of subjects following CABG surgery together with the experience of surgery and the perceived benefits to health the following summary findings have been identified:-

- Approximately 55% of subjects were relieved of angina and 36.3% relieved of breathlessness symptoms at follow-up assessment. The mean score of those with symptoms was highly significantly reduced (angina $p<0.001$, breathlessness, $p=0.02$).

- A comparison of self-reported levels of angina and breathlessness symptoms given at phase I to subjects' recall of level of these symptoms at phase II, were not statistical different and would suggest that this may be a useful clinical outcome measure to assess symptomatic relief following CABG surgery.

- Uncorrected CHD risk factors were present; 60.5% of subjects had elevated systolic blood pressure, 43.6% elevated diastolic blood pressure, 56.1% elevated plasma cholesterol, 81% increased BMI, 12.7% with diabetes mellitus and 24.9% were currently smoking cigarettes.

- The majority of subjects had three and four uncorrected CHD risk factors a similar picture as preoperatively.

- The majority of subjects attended cardiac rehabilitation. There was no difference ($p=0.25$) between those who attended cardiac rehabilitation partially or in full compared to non-attendance in terms of the presence of uncorrected CHD risk factors, presence or absence of angina or breathlessness or level of symptoms if present.

- Subjects who attended cardiac rehabilitation had improved health status as measured by the SF-36 scale across all eight health domains. These improvements were highly significantly better in the general health domain and significantly higher in the physical function, physical role limitation and social function domains for attendees compared to non-attendees.

- Subjects valued the opportunity to attend cardiac rehabilitation programmes with particular reference to confidence building and the companionship of others with similar health problems.

- Health status (mean SF-36 II scores) was statistically significantly ($p<0.001$) improved across all of the eight domains. The majority of the SF-36 scores either improve or deteriorate, except for physical role limitation and emotional role limitations, where approximately half of the subjects have no change in their score.

- Improved levels of health (SF-36-II scores) following CABG surgery were associated with a higher social network score and older subjects.

- Lower levels of health (SF-36-II scores) are largely influenced by presence of angina and breathlessness symptoms at phase II.

- Lower levels of health (SF-36-II scores) were associated to a lesser extent by current or past smoking, elevated plasma cholesterol levels, a high socio-

economic deprivation category, a higher number of uncorrected CHD risk factors, higher alcohol intake, diabetes mellitus and external health locus of control.

- *The benefits of surgery were described in terms of removal of a death sentence and the freedom to get on and live a life as they wished.

- *The experience of CABG surgery was viewed as a very difficult process with 'lay support' being a valued and important source of help.

* These subjective accounts were part of a much richer qualitative picture that emerged in the study interviews and has been outlined in detail within results in chapter 6.

Chapter 7

7.1 Introduction

In this chapter the relationship between preoperative factors measured at the baseline assessment in phase I of the study have been examined in terms of their influence on the outcome variables measured at the phase II assessment, approximately 16 months following CABG surgery. The analysis was undertaken to identify the factors that most influence post surgical health status as measured by SF-36-II health domain scores, freedom from angina and breathlessness symptoms at phase II and, when present, the severity of these symptoms. As a precursor to this analysis, the eight SF-36-II domains and the phase II angina and breathlessness self reports were correlated with the range of phase I variables (Appendix XII).

7.2 Phase II Presence of Angina and Breathlessness Symptoms

At phase II assessment, 30.8% of all subjects reported that they had no angina or breathlessness symptoms, 5.4% reported that they had angina but no breathlessness and 24.4% reported that they had breathlessness without angina. The remainder (39.6%) reported that they had both angina and breathlessness symptoms. The number and percentage of subjects with or without angina and breathlessness symptoms at phase II are presented by gender in table 7.1.

Table 7-1. Number of subjects (percentage) with or without angina and breathlessness symptoms at phase II, by gender

variable	male angina II (yes) n=149	male angina II (no) n=149	female angina II (yes) n=33	female angina II (no) n=33
breath II (yes)	55 (36.9%)	36 (24.2%)	17 (51.6%)	8 (24.2%)
breath II (no)	10 (6.7%)	48 (32.2%)	0 (0.0%)	8 (24.2%)

In this chapter, phase II angina and breathlessness scores are classified in terms of three related but different variables. In tables 7-2 and 7-3 correlations between phase I variables and the category variables angina II (yes/no) and breathlessness II (yes/no) are presented.

In Appendix XVIII tables C and D present correlations between phase I variables and the continuous variables angina II (+ve) and breathlessness II (+ve) which represents the symptom severity score when present. Finally, tables E and F present correlations between phase I variables the reported angina and breathlessness scores at phase II (continuous variables). These scores differ from the II (+ve) scores in that they contain 0 as a possible state. As in previous correlation tables, the statistically significant correlations are identified with p values in bold font.

Table 7-2. Bivariate correlation* (Pearson) table of angina II (yes/no) and breathlessness II (yes/no) scores with SF-36-I domains

SF-36-I domain	Angina II (yes/no)	breath II (y=1/n=0)	SF-36-I domain	Angina II (yes/no)	breath II (yes/no)
Bodily pain	**-0.246** (174)	-0.078 (174)	**Energy/ vitality**	**-0.237** (172)	**-0.169** (172)
General health	-0.009 (173)	-0.088 (173)	**Mental health**	**-0.241** (172)	**-0.228** (172)
Physical function	**-0.166** (173)	-0.140 (173)	**Role: emotional**	-0.089 (172)	-0.124 (172)
Role: physical	-0.043 (172)	**-0.178** (172)	**Social function**	**-0.199** (173)	-0.040 (173)

* Significant correlations are indicated in bold

Table 7-3. Bivariate correlation* (Pearson) table of angina II (yes/no) and breathlessness II (yes/no) scores with non-SF-36-I phase I variables

Variable	angina II (yes/no)	Breath II (yes/no)	variable	Angina II (yes/no)	breath II (yes/no)
age (yrs)	-0.129 (180)	**-0.169** (180)	age-at-onset (yrs)	-0.112 (164)	**-0.173** (164)
alcohol I (units/week)	-0.069 (155)	0.089 (155)	angina I (yes/no)	0.067 (178)	0.024 (178)
Tchol I (mmol/l)	-0.123 (159)	-0.056 (159)	breath I (yes/no)	-0.050 (178)	0.008 (178)
angina I (+ve)	-0.072 (171)	0.039 (171)	breath I (+ve)	-0.026 (165)	0.117 (165)
depcat	0.008 (182)	0.072 (182)	waist I	0.070 (182)	0.047 (182)
DBP I (mm Hg)	0.011 (179)	0.039 (179)	SBP I (mm Hg)	-0.058 (179)	-0.093 (179)
HLOC I	0.061 (154)	0.034 (154)	SOC I	-0.110 (160)	**-0.230** (160)
past smoker I	0.045 (182)	-0.096 (182)	current smoker I	0.042 (182)	**0.151** (182)
risk I	-0.035 (159)	0.006 (159)	diabetes mellitus	0.021 (182)	0.012 (182)

* Significant correlations are indicated in bold

7.3 Analysis of self-reported angina symptoms at phase II

At phase II, 100 (54.9%) subjects indicated that they were completely free of angina whereas 82 (45.1%) still had varying degrees of angina. The profile of the subjects whose angina was relieved was compared to those who remained symptomatic. The statistically significant differences between both groups are described in tables 7-4 and included five SF-36-I domains and age. However, no significant differences were shown between the two groups in the phase I measures of age at onset of CHD, alcohol consumption, angina self-rated score, BMI, breathlessness self-rated score, current and past smoking status, deprivation category, presence of diabetes mellitus, NYHA score, plasma cholesterol, diastolic and systolic blood pressures, waist

circumference, general health, Health Locus of Control, emotional role limitation, the number of CHD risk factors above target levels, physical role limitation, social network score, waist circumference, weight and number of vessels by-passed.

Table 7-4. Analysis of statistically significant phase I variables between those with and those without angina symptoms at phase II

phase I variable	number of subjects	angina II (no) mean (SD)	number of subjects	angina II (yes) mean (SD)	p-value
age (yrs)	99	59.1 (6.6)	81	57.1 (8.4)	**0.008**
Bodily pain	95	50.7 (26.2)	79	38.1 (23.4)	**0.001**
Energy/vitality	93	41.4 (19.4)	79	31.6 (20.7)	**0.002**
Mental health	93	65.5 (17.3)	79	56.5 (19.0)	**0.001**
Physical function	94	39.8 (23.6)	79	31.8 (23.7)	**0.029**
Social function	94	55.1 (26.4)	79	44.1 (28.0)	**0.009**

Significant correlations are indicated in bold

7.4 Analysis of self-reported breathlessness symptoms at phase II

At phase II, 66 (36.3%) subjects reported that they were free of breathlessness whereas 116 (63.7%) still had varying degrees of breathlessness. The profile of phase I variables were compared between those subjects whose breathlessness was relieved and those who remain symptomatic. The statistically significant differences between both groups are described in table 7-5 and included age, age at onset of CHD and four SF-36-I domains. However, no significant differences were found between those who were relieved of breathlessness at phase II and those who were not in respect of the phase I measures of alcohol consumption, angina, BMI, breathlessness, deprivation category, past smoking status, presence of diabetes mellitus, plasma cholesterol, diastolic and systolic blood pressures, bodily pain, general health, social function, physical function, emotional role limitation, number of CHD risk factors above target levels (risk I), health locus of control, waist circumference and number of vessels by passed.

Table 7-5. Differences in phase I variables between those with and those without breathlessness symptoms at phase II

phase I variable	number of subjects	breath II (n=0) mean (SD)	number of subjects	breath II (y=1) mean (SD)	p-value
age (yrs)	65	59.9 (6.5)	115	57.2 (7.9)	**0.023**
age-at-onset (yrs)	60	54.7 (7.2)	104	51.9 (7.8)	**0.027**
SOC I	58	26.2 (6.1)	102	23.0 (7.0)	**0.003**
current smoker I	66	0.22 (0.44)	116	0.26 (0.44)	**0.043**
Energy/vitality	62	41.5 (20.9)	110	34.3 (20.0)	**0.027**
Mental health	62	67.0 (18.1)	110	56.5 (18.2)	**0.003**
Role: physical	63	22.6 (37.8)	109	11.0 (26.7)	**0.020**

7.4.1 Regression analysis for angina and breathlessness scores at phase II

Angina II and breathlessness II were regressed linearly against phase I variables. Approximately 12.5% of the variation in angina II was explained by the phase I variables age (X_1) and bodily pain (X_2) while approximately 12.1% of breathlessness II was explained by the presence of diabetes mellitus (X_3) and the phase I variables mental health (X_4) and social networks score (X_5). The regression analyses for the phase II angina and breathlessness scores were based on 171 subjects. It was shown that:-

$$AnginaII = 4.409 - 0.038X_1 - 0.021X_2$$

where the p-values for the null hypothesis that the constant term and coefficients of X_1 and X_2 in this regression are not significantly different from zero are

variables	constant	X_1	X_2
p-value	<0.001	0.024	<0.001

The regression analysis for breathlessness II was;-

$$BreathlessnessII = 5.172 + 0.168X_3 - 0178X_4 - 0.231X_5.$$

where the p-values for the null hypothesis that the constant term and coefficients of X_3, X_4 and X_5 in this regression are not significantly different from zero are

variables	constant	X_3	X_4	X_5
p-value	<0.001	0.026	0.021	0.003

These regression formulae indicated that the presence of angina at phase II was reduced for older subjects with higher baseline bodily pain while breathlessness at phase II was generally worse for subjects with diabetes mellitus and was improved for subjects with high baseline social network and mental health scores.

7.5 Correlation between SF-36-II domains and phase I variables

Correlation coefficients between SF-36-I and SF-36-II domains are listed in Appendix XV. The scores for each of the eight SF-36-II domains have a positive correlation coefficient with each of the corresponding SF-36-I domains. Furthermore, the correlations are not necessarily strongest between the same domains SF-36 at phases I and II. The correlation coefficient between baseline and follow up emotional role limitation scores is 0.315 whereas the correlation coefficient between follow up emotional role limitation and baseline mental heath is 0.379 representing a stronger relationship.

The correlations between the SF-36-II domains and other statistically significant phase I variables are presented in tables 7-6. A correlation coefficient exceeding 0.15 in magnitude corresponds to a statistically significant correlation for which there is a less than 5% probability that the realised correlation factor arose by chance. Phase I variables that exhibit high correlation coefficients for a particular SF-36-II domain are potential candidates for predictor variables in a linear regression analysis which tests the independent contribution of the individual factors.

Current smoking and past smoking were both negatively correlated with all the SF-36-II domains although the correlation factors for past smoking were smaller than those for current smoking. Therefore it can be inferred that in respect of all the SF-

36-II domains, there is a graduated beneficial effect in the progression from current smoker to past smoker and finally non-smoker.

Table 7-6. Bivariate correlation* (Pearson) table of SF-36-II domains with other phase I variables

Variable	Bodily Pain	Energy Vitality	General Health	Mental Health	Physical Function	Role: Emotional	Role: Physical	Social Function
alcohol I (units/week)	-0.020 (151)	**-0.184** (152)	**-0.176** (153)	**-0.172** (152)	-0.089 (153)	-0.060 (146)	-0.028 (150)	-0.088 (152)
age	0.108 (172)	**0.149** (177)	**0.181** (178)	0.120 (177)	0.055 (178)	-0.005 (169)	0.072 (174)	0.140 (177)
age-at-onset (yrs)	0.136 (159)	**0.159** (160)	**0.190** (161)	0.108 (160)	0.080 (161)	0.080 (153)	0.111 (159)	**0.163** (160)
diabetes mellitus	-0.068 (178)	-0.006 (179)	**-0.159** (180)	-0.101 (179)	**-0.197** (180)	**-0.279** (170)	**-0.236** (176)	-0.090 (179)
depcat	-0.037 (178)	**-0.196** (179)	-0.096 (180)	**-0.177** (179)	**-0.229** (180)	-0.084 (170)	**-0.163** (176)	**-0.155** (179)
HLOC I	0.157 (150)	-0.009 (152)	0.070 (152)	0.042 (152)	0.040 (152)	-0.017 (146)	0.006 (152)	0.060 (152)
risk I	-0.001 (155)	-0.082 (156)	-0.025 (157)	-0.103 (156)	-0.085 (157)	**-0.199** (148)	-0.144 (154)	-0.082 (156)
Current smoker I	**-0.164** (178)	**-0.184** (179)	**-0.188** (180)	**-0.210** (179)	-0.145 (180)	**-0.243** (170)	-0.219 (176)	-0.167 (179)
Past smoker I	-0.115 (178)	-0.146 (179)	-0.051 (180)	-0.112 (179)	-0.069 (180)	**-0.200** (170)	**-0.157** (176)	-0.106 (179)
SOC I	**0.250** (156)	**0.265** (157)	**0.245** (158)	**0.325** (157)	**0.357** (158)	**0.189** (152)	**0.225** (158)	**0.254** (157)

* Significant correlations are indicated in bold

Older subjects generally have higher SF-36-II domain scores overall, with statistically significant higher scores for the domains energy/vitality, general health and social function. All SF-36-II domains have statistically significant positive correlations with the social network score. Conversely, diabetes mellitus, deprivation category, alcohol consumption and number of CHD risk factors (as defined in table 5-5) are all negatively correlated with SF-36-II scores to varying degrees.

Health locus of control has little impact on SF-36-II scores except for bodily pain with which it is positively correlated. Angina I self-rated score, breathlessness I self-rated score, cholesterol I, BMI-I, waist I, NYHA category, number of vessels by-passed, diastolic and systolic blood pressures and age are not significantly correlated with the SF-36-II domains, and, therefore, have not been included in table 7-6.

7.6 Multivariate Linear Regression Analysis

Each SF-36-II domain was regressed linearly against a series of phase I variables. The correlation tables in Appendices XV, XVII and table 7-10 provided guidance as to the most appropriate variables to include in the regression analysis. However, the final regression formula was based only on those phase I variables whose coefficients of regression are statistically significant in the sense that their associated p-value is less than or equal to 0.05. The extent to which the regression equation explains the variability of the predicted value of the data about the mean value of the dependent variable was also provided. The histogram of the residuals, graphs of residuals versus fit and some normal scores plots are included in Appendix XVI. Linear regression equations were calculated for each SF-36 II domain. The results are presented in table 7-7 and the detailed calculations are presented in full detail in Appendix XVI.

Table 7-7. Summary of the statistically significant phase I variables in the regression of each SF-36 domain at phase II

SF-36-II domain	R-square value	Size of Sample	Baseline Contributing Variables	Direction of influence
Bodily pain	13.6%	155	Bodily Pain	+
			Social Networks	+
Energy/ vitality	24.6%	135	Energy Vitality	+
			Social Networks	+
			Alcohol	-
General health	15.7%	155	Energy Vitality	+
			Social Networks	+
			Diabetes Mellitus	-
			Age	+
Mental health	21.9%	135	Mental Health	+
			Social Networks	+
			Current smoking	-
			Alcohol	-
Physical function	29.5%	157	Physical Function	+
			Mental Health	+
			Social Networks	+
			Diabetes Mellitus	-
			Waist	-
			Weight	+
Role: emotional	25.9%	160	Role: Emotional	+
			Mental Health	+
			Diabetes Mellitus	-
			Past smoking	-
Role: physical	25.9%	160	Role: Physical	+
			Social Function	+
			Diabetes Mellitus	-
			Current smoking	-
Social function	15.1%	156	Social Function	+
			Social Networks	+
			Current smoking	-
Mean score	26.1%	148	Mean Score	+
			Social Networks	+
			Diabetes Mellitus	-
			Current smoking	-

7.7 Changes in SF-36 Scores Winners and losers

The phase II results have shown that although the mean score for each SF-36-II domain was either very/highly significantly increased, often approximately a quarter of the subjects actually experience a decrease in their SF-36-II score after CABG surgery.

For each SF-36 domain, scores for subjects were compared between those who improved their score with those whose score deteriorated. All subjects who responded to SF-36-I and SF-36-II questionnaires were partitioned *for each domain* into those who improved their score at phase II (group A), those who maintained their score at phase II (group N) and those whose score was decreased at phase II (group B). These three groupings are used for clarity in the subsequent presentation of results although, the actual composition of the groups were different for each SF-36 domain. Numbers of subjects in group A, group N and group B are already given in table 6.10.

For each of the eight SF-36 domains, the groups of subjects who improved their scores (group A) were compared to those whose scores deteriorated (group B), firstly in terms of their SF-36-I scores and, secondly in terms of their other phase I variables. The results are presented in table 7-8.

Table 7-8. Statistically significant differences in phase I scores between those who increased their phase II SF-36 score (group A) in any particular domain and those who decreased their phase II SF-36 score (group B) in that same domain.

SF-36-II domain	Significant difference in phase I variables	Group A mean (SD)	Group B mean (SD)	p-value
Bodily pain	Bodily Pain	37.7 (22.4)	58.2 (23.0)	**<0.001**
	Energy/vitality	33.7 (21.7)	43.3 (17.5)	**0.010**
	Physical function	33.5 (23.5)	42.2 (24.3)	**0.041**
	Social function	45.3 (27.1)	60.3 (26.6)	**0.002**
	No. of vessels by-passed	3.26 (0.89)	2.96 (0.84)	**0.044**
Energy/ vitality	Energy/vitality	32.9 (21.4)	46.3 (15.9)	**<0.001**
	Social function	46.6 (27.5)	59.3 (25.0)	**0.008**
General health	General health	35.6 (17.3)	43.1 (16.1)	**0.016**
	Mental health	63.3 (18.9)	55.0 (17.2)	**0.015**
	Role: emotional	42.1 (44.7)	23.1 (37.6)	**0.017**
	Alcohol	6.3 (10.2)	9.8 (13.9)	**0.035**
Mental health	Energy/vitality	33.7 (21.6)	40.4 (18.6)	**0.046**
	Mental health	54.7 (18.5)	68.6 (15.3)	**<0.001**
	Alcohol	4.9 (7.7)	10.6 (15.7)	**0.007**
Physical function	Bodily pain	42.1 (24.1)	50.9 (26.9)	**0.048**
	Physical function	31.8 (21.8)	48.9 (23.7)	**<0.001**
	Role: physical	11.2 (26.3)	25.0 (39.9)	**0.012**
	Social networks	24.8 (6.7)	21.9 (7.4)	**0.031**
Role: emotional	Role: Emotional	14.0 (24.4)	74.1 (29.4)	**<0.001**
	Social function	48.6 (25.8)	60.2 (24.2)	**0.048**
	Diabetes mellitus	5.3%	24.1%	**0.010**
	Current smoking	15.8%	34.5%	**0.050**
Role: physical	Physical function	38.1 (19.4)	58.1 (19.7)	**0.001**
	Role: physical	8.5 (19.1)	61.5 (33.3)	**<0.001**
	Social function	54.6 (26.9)	78.6 (16.0)	**0.003**
	Diabetes mellitus	4.4%	23.1%	**0.019**
	NYHA score			**0.050**
Social function	Bodily pain	41.1 (23.9)	50.4 (25.5)	**0.039**
	Energy/vitality	34.0 (21.2)	43.2 (17.3)	**0.018**
	Social function	42.4 (24.2)	63.8 (23.9)	**<0.001**
	Age at onset	53.8 (7.9)	50.7 (6.8)	**0.041**

* Significant correlations are indicated in bold

7.7.1 Subjects whose SF-36 score remained unchanged

For the SF-36 domains physical role limitation and emotional role limitation there were approximately 50% of subjects whose score did not change that is in the previously defined group N. There were only a small number of subjects who had no changes to their scores in the other SF-36 domains (approximately 10 %) and these have no been analysed because the number are small. For the two SF-36 domains of role limitation physical and emotional, the groups of subjects whose score did not change (group N) were compared to those whose scores either improved (group A) or deteriorated (group B), in terms of their SF-36-I scores and their other phase I variables. The results are presented in table 7-9.

Table 7-9. Statistically significant differences in phase I scores between those whose SF-36 score remained unchanged (group N) and those who increased (group A) or decreased (group B) their phase II SF-36 score in that same domain.

SF-36-II domain	Significant difference in phase I variables	Group A mean (SD)	Group N mean (SD)	Group B mean (SD)	p-value
Role: Emotional	Role: Emotional		42.1 (14.8)	74.1 (29.4)	**<0.001**
	Role: Emotional	14.0 (24.4)	42.1 (14.8)		**<0.001**
Role: Physical	Bodily pain		39.4 (24.3)	61.5 (25.1)	**0.003**
	Energy/vitality		32.6 (19.9)	51.2 (18.7)	**0.002**
	Physical function		31.9 (25.8)	58.1 (19.7)	**0.001**
	Role: emotional		27.1 (40.1)	70.5 (33.4)	**<0.001**
	Role: physical		14.0 (34.2)	61.5 (33.3)	**<0.001**
	Social function		42.8 (26.5)	78.6 (16.0)	**<0.001**
	Bodily pain	48.0 (24.3)	39.4 (24.3)		**0.030**
	Energy/vitality	39.9 (20.8)	32.6 (19.9)		**0.028**
	Mental health	67.3 (17.6)	55.8 (18.7)		**<0.001**
	Role: emotional	45.6 (46.0)	27.1 (40.1)		**0.009**
	Social function	54.6 (26.9)	42.8 (26.5)		**0.007**

7.8 Number of SF-36 domains improved

The histogram in figure 7-1 indicates the percentage of subjects who have improved or deteriorated health status as measured by the number of SF-36 domain scores that improved between phases I and II of the study.

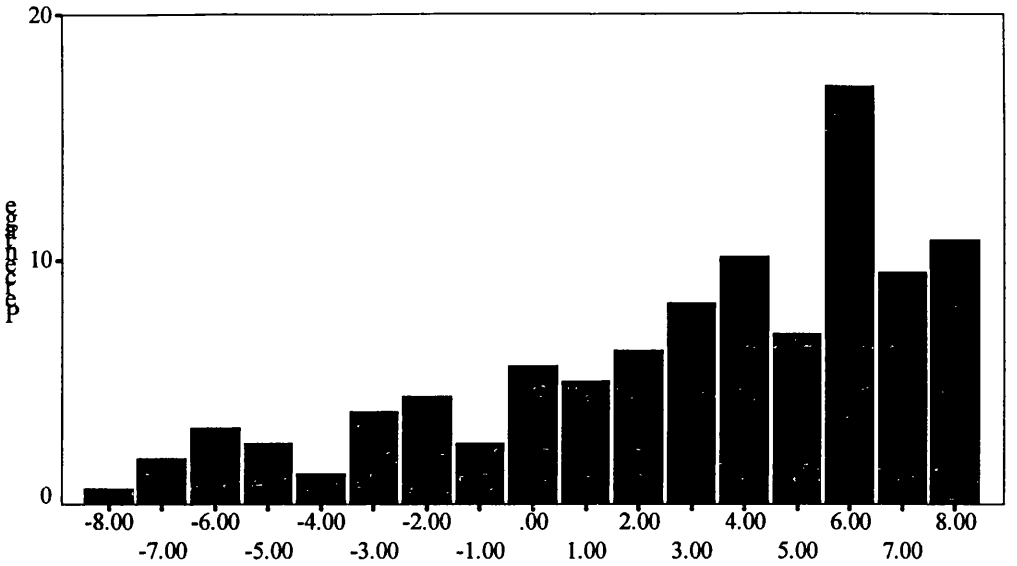

Figure 7-1. Number of SF-36 domains improved at phase II assessment

The number subjects who improve their SF-36-II scores is negatively correlated with each SF-36-I domain indicating that those who have the greatest improvement in terms of maximising the number of SF-36 domains in which they have an increased score also tend to have the lowest SF-36-I domain scores.

7.9 Conclusions

This chapter has presented results that address the research question relating to examining the associations between pre-operative health status subject measured on the main outcome measures of health status, namely SF-36 II scores and angina and breathlessness symptoms.

- Older subjects more likely to be relieved of angina and breathlessness symptoms ($p<0.001$).

- It is more difficult to get total relief from breathlessness than angina symptoms.

- Continued breathlessness symptoms are more common in smokers and subjects with low social network scores.

- Past smoking, socio-economic deprivation category, alcohol intake, diabetes mellitus health locus of control, plasma cholesterol or increased blood pressure have no significant effect on whether a subject is totally relieved of angina or breathlessness symptoms following CABG surgery.

- When symptoms are not relieved totally, subjects with higher level of angina symptoms before surgery and diabetes mellitus have selectively less relief of breathlessness symptoms but these factors have no impact on angina symptoms.

- The presence of angina at follow-up was independently related to younger age of subject and bodily pain before surgery; breathlessness at follow-up was independently explained by the presence of diabetes mellitus, reduced phase I mental health and higher social networks score at phase I.

- Subjects with lower health levels (SF-36) prior to CABG surgery are less likely to be relieved of angina or breathlessness ($p<0.001$).

- Higher levels of health (SF-36) prior to CABG surgery are associated with improved health (SF-36) scores at phase II.

- Using SF-36-II scores as an outcome variable in a linear regression model showed that individual scores depend strongly on particular SF-36-I scores and selective non-SF-36 variables, the most important of which are social network score, presence of diabetes mellitus and current smoking status but to a lesser extent advanced age, alcohol consumption and waist circumference.

Chapter 8

8.1 Aims of this study

The general aim of this study was to examine the changes in health status in patients undergoing CABG surgery. In order to do this, three specific questions were formulated as study objectives. Firstly, to assess the health status of subjects prior to CABG surgery; secondly, to measure the health status of subjects following CABG surgery, and thirdly, to examine the relationship between pre-operative variables including health status and subsequent health status following surgery. The study design was descriptive, and involved clinical assessment, before and after cardiac surgery with case note retrieval of information related to surgery undertaken between these two assessments. In order to answer the research questions, data were collected on demographic and clinical characteristics of the subjects, CHD risk factors, general health and well-being status, CHD symptomatic ratings, health locus of control, social networks and self-reported views of health and expectations of surgical outcome. Health status following CABG surgery has been considered in terms of the following measures: Change in SF-36 scores (improved, same or deteriorated), final SF-36 score measured at follow-up assessment, angina and breathlessness symptoms (presence or absence) and angina and breathlessness symptoms (self-rated score when symptom present) at follow-up assessment.

8.2 General discussion of results

The study cohort consisted of 215 subjects approximately one-quarter female and three-quarters male with a mean age of 58 years and a range of ages from 39 years to 79 years. The gender balance of the study subjects was similar to that of the GGHB population who had surgery in the same year (1995) but the mean age was four years younger. The subjects were drawn largely from the east end of Glasgow and were from areas of higher socio-economic deprivation (McLoone, 1994) than the overall GGHB patient database. Surgical complications have been shown to be higher in younger individuals (<40years old) (Wagner, 1996) and older individuals (>70 years old) (Weintraub et al, 1991; Khan et al, 1992) compared to that the age groups in between. It could therefore be expected that the outcome for the study subjects may be less favourable than for all patients undergoing CABG surgery because of the age

profile of the subjects. Similarly, event rates and survival in individuals with CHD from areas of high socio-economic deprivation have been shown to be significantly increased compared to individuals from the least deprived areas (Carstairs and Morris, 1991; Morrison et al, 1997). Therefore the subjects in this study had an age profile and socio-economic deprivation status that confers a higher risk of adverse outcome. Generalisability of the results should take into account the age and socio-economic profile of the study subjects. This is discussed in more detail in section 8.14.

The majority of patients underwent triple artery bypass surgery and over 80% of those subjects had insertion of a single internal mammary artery that has been associated with the most favourable long-term patency rates (Loop, 1996). Peri-operative mortality rate was 4.8% overall, but statistically significantly higher for females than males (p=0.018) confirming the increased operatively mortality in women in other studies (Weintraub et al, 1993; Brandrup-Wognsen et al, 1996). The total number of females in the study was small (n=44) and the number who died in the perioperative period was also small (n=5). There was no statistically significant difference in age, deprivation category, presence of diabetes mellitus or the number of risk factors present, including smoking, between those women who died and those who survived surgery, although it is most likely that these numbers were too small to undertake meaningful statistical analysis. A total of 183 subjects (85.1%) completed follow-up assessment in phase II of the study, which was undertaken approximately 16 months after surgery.

8.3 Health status as measured by CHD related symptoms

8.3.1 Angina and breathlessness symptoms before CABG surgery

Prior to surgery the mean angina and breathlessness scores for females were statistically significantly higher than for males (4.8 (4.3) v 3.9 (3.6), p=0.007 (0.038)). More severe preoperative levels of angina in women compared to men have been reported in other work (Farrer et al, 1997) and the results from this study have supported this finding with women who were selected for surgery, reporting more severe symptoms and therefore being less well than men. Although CHD symptoms are only one index of disease severity in terms of clinical management,

they represent an important determinant of care decisions. The studies that have examined investigation patterns for individuals with CHD, reported that women with CHD are less likely to be referred for investigation of CHD symptoms at an early stage (Ayanian and Epstein, 1991; Limacher, 1996). This may lead to women having more severe levels of symptoms at referral for CABG surgery.

The angina and breathlessness self-rated mean scores for the study subjects as a group were highly significantly correlated ($p<0.001$). Linear regression analysis showed that the total variation in baseline angina scores explained 25% of the male and 27.5% of the female breathlessness score. In effect, severe breathlessness symptoms (i.e. breathlessness self reports above the mean) were likely to be accompanied by severe angina (angina scores in excess of the mean) symptoms and vice-versa confirming the relationship between these two symptoms reported by others (Cook and Shaper, 1989).

Angina symptoms were also assessed using the NYHA grading scale provided by the patients' cardiologist. Approximately 41% and 43% of patients were allocated to grades 2 and 3 respectively, representing moderate levels of symptom severity. In practice, the NYHA grades did not show any correlations with other measures of health and symptoms in the statistical analysis. This may indicate a lack of sensitivity as a measure of symptom levels.

8.3.2 Angina and breathlessness symptoms after CABG surgery

At follow-up assessment, 54.9% of subjects reported no angina symptoms. However, those subjects (45.1%) who reported angina symptoms at follow-up assessment, had a mean score that was highly significantly reduced (4.2 v 2.8, $p<0.001$). The percentage of subjects with relief of angina was considerably lower than reported in other studies that documented presence of chest pain at one year in 10% of subjects (Pocock, 1996) and 10.9% of subjects (CABRI Trial Participants, 1995) and at two years in 42% of subjects (Brandrup-Wognsen et al, 1997). The latter study investigated subjects with chest pain and concluded that the pain correlated with the occurrence of chest pain during exercise testing but not with signs of myocardial ischaemia. Therefore because chest pain may have its origin from many sources

further investigation of the exact nature of the pain would be required to confirm its relationship to myocardial ischaemia. Early return of angina symptoms following CABG surgery has been shown, over a six year follow-up, to be associated with an increased risk of myocardial infarction and greater need for re-operation although it did not affect survival rates (Cameron et al, 1995).

Absence of breathlessness symptoms was reported by 36.3% of the subjects at follow-up assessment. Subjects who reported experiencing breathlessness symptoms (63.7%) at follow-up assessment had mean self-rated scores significantly reduced (4.0 vs 3.5, $p=0.021$). Since the elimination rate for angina (54.9%) was considerably greater than that for breathlessness (36.3%), approximately a quarter of the cohort following CABG surgery experienced breathlessness symptoms without angina symptoms. It is however also possible that breathlessness symptoms may originate from another pathology such as emphysema or lung dysfunction. However, the strong correlation of the angina and breathlessness scores (section 5.6) indicate that they were both related and thus likely to be cardiac in origin a relationship that has been described in the medical literature (Cook and Shaper, 1989).

8.3.3 Correlation of angina and breathlessness symptoms with other phase I variables

The positive and negative trends of the statistically significant correlations of phase I variables with angina and breathlessness symptoms at follow-up assessment are presented in table 8.1.

Table 8-1. Statistically significant correlations ($p<0.05$) of angina and breathlessness symptoms at phase II versus phase I variables

phase I variable	angina-II (yes/no)	breath-II (yes/no)	angina-II (+ve)	breath-II (+ve)
Bodily pain	-ve		-ve	-ve
Energy/vitality	-ve	-ve	-ve	-ve
Mental health	-ve	-ve	-ve	
Physical function	-ve			
Role: physical		-ve		
Social function	-ve		-ve	-ve
diabetes mellitus				+ve
current smoking I		+ve		
age		-ve		
age at onset		-ve		
SOC I		-ve		
angina I (+ve)				+ve

The exclusive presence of negative correlations with the SF-36-I domains of table 8.1 indicated that there was a marked tendency for subjects with high (as measured against the mean) scores in the domains bodily pain, energy and vitality, mental health and social function to have their angina either eliminated or significantly relieved as a result of CABG surgery. Elimination of angina was enhanced further if their baseline physical function score was also high but, rather interestingly, no other factors appeared to have a statistically significant impact on outright elimination or level of angina symptoms at follow-up assessment. This contrasts with the work of Pocock et al, (1996) who showed that high levels of angina before surgery were related to return of angina after surgery.

The correlation analysis for breathlessness symptoms presented a more diverse picture. Again, all the significant SF-36-I domains were negatively correlated with the breathlessness variables. Subjects with high SF-36-I scores in the domains energy/vitality, mental health and physical role limitation were more likely to have

their breathlessness eliminated after CABG surgery than others; that is, people who reported better levels of health. This may help guide clinicians when they refer patients for surgery. Moreover, the significant correlations with the non-SF-36-I variables suggests that health after surgery is improved further if the subjects are older (with an older onset of CHD), are not current smokers and enjoy a high level of social support networks.

If breathlessness was not eliminated after CABG surgery, then subjects with high scores in bodily pain, energy and vitality and social function at baseline assessment were likely to experience the greatest relief of breathlessness, especially if they happen to have a low angina score and do not suffer from diabetes mellitus. High baseline angina scores and the presence of diabetes mellitus independently increased the breathlessness score after CABG surgery. Higher levels of health status as measured by domains of the SF-36 scores, older subjects, not smoking, absence of diabetes mellitus and higher levels of social support before surgery were all associated with better outcome in terms in relief of breathlessness symptoms. This may be helpful information in terms of selections of patients for surgery as poorer outcomes in terms of cardiac events have been reported in smokers (Herlitz et al, 1997), individuals with diabetes mellitus (Risum et al, 1996) and those with lower levels of social support networks (House et al, 1988; Berkman, 1995).

8.3.4 Retrospective rating of angina and breathlessness symptoms

At phase II assessment the subjects were also asked to rate the level of angina and breathlessness symptoms at phase I, using the same self-rating scale. Interestingly, their recollection of symptom levels compared well with the actual reported symptom level at baseline (angina:p=0.274; breathlessness:p=0.196) and would suggest that this may be a useful measure of clinical improvement after surgery in the absence of any pre-operative assessment.

8.3.5 Regression analysis for angina and breathlessness scores at phase II

A linear regression analysis of angina II and breathlessness II against all phase I variables indicated that bodily pain and age were the most important predictors of post-operative levels of angina. The presence or absence of diabetes mellitus, the

mental health score and social networks score were the most important factors influencing post-operative levels of breathlessness. Older age and higher bodily pain score were beneficial to the relief or reduction of post-operative angina. The presence of diabetes mellitus was detrimental to the relief or reduction of breathlessness while higher mental health and higher social network scores both contribute beneficially to the relief or reduction in post-operative breathlessness.

8.4 Health status as measured by the multi-dimensional SF-36 questionnaire

The SF-36 health measure was used as the main health outcome measure following CABG surgery. The scores that were generated showed that the measure was able to differentiate between individuals at a single time point and in the same individuals over time thereby satisfying a necessary criteria for a health status measure (Oldridge, 1997) for health outcome assessment (Davies et al, 1994). In other studies, the SF-36 instrument has been shown to be capable of discriminating between different health states (Lyons et al. 1994b). The phase I SF-36 summary statistics are presented in table 5-8. The mean study scores ranged from a minimum of 14.7 in domain role limitation due to physical factors to 61.1 in mental health, which were generally low scores. Subjects from higher socio-economic deprivation groups had statistically significantly lower scores for five of the eight SF-36-I health domains, confirming the well established relationship between high levels socio-economic deprivation and ill-health (Smith et al, 1995).

The profile of baseline SF-36 scores were compared with two other groups of patients with established CHD (Ware Jr, 1993). For all domains of health described by the SF-36-I scores, the study cohort had statistically highly significantly lower scores than both the other patient groups with CHD ($p<0.001$). The SF-36 scores at phase II assessment were compared to a general population sample and show that the study subjects had statistically significant lower scores ($p<0.001$) at follow-up assessment. A summary of these comparisons is presented in figure 8.1.

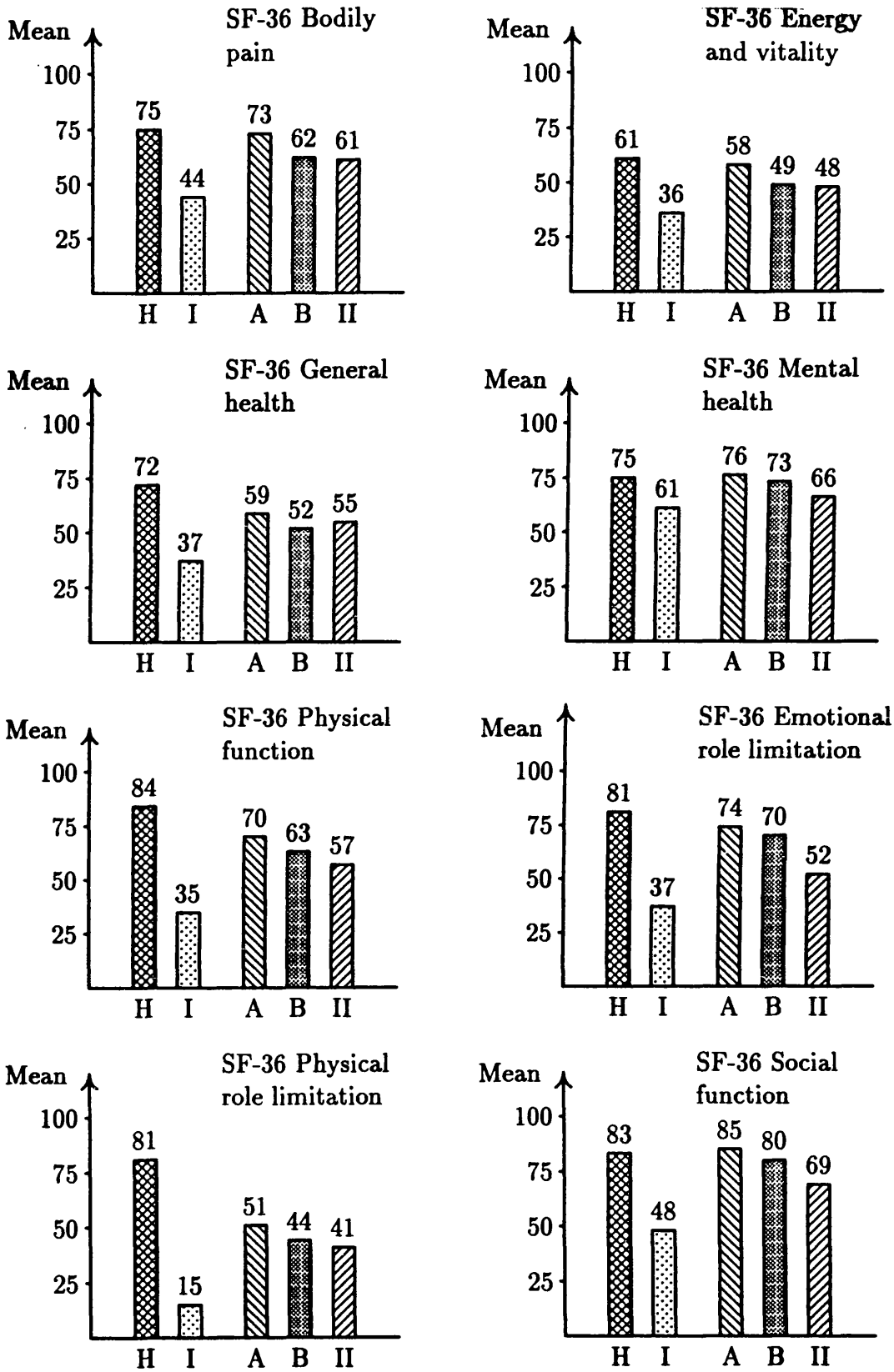

Figure 8-1. Histograms of the mean scores of the eight SF-36 domains in the study subjects at phase I and phase II of the study, a general population group (H) and two CHD patient groups (A & B) previously described (section 5.11.1). Phase I and II scores are improved ($p<0.001$) but lower than the other three comparison groups

Examination of the gender differences and the domains of the SF-36-I are presented in table 5-10. Mean female scores were significantly lower than male scores for mental health, physical function and social function. There were no reports of gender differences in SF-36 scores reported in the literature and these results may reflect the lower levels of health as a result of more severe levels of symptoms documented in this study and reported elsewhere (Farrer et al, 1997).

8.4.1 Answering the SF-36 questionnaire

As highlighted in the literature (Barrett, 1997), problems in interpretation and completion by the user can be a problem. Three general issues arose that posed difficulty for some subjects when attempting to answer the questions in the SF-36 questionnaire as identified in the thematic analysis of the interviews. The detailed comments are presented in sections 8.15.4-8.15.7. Firstly, health status was viewed as being dependent on other variables and as a result was changeable. Secondly, although the subjects were not specifically asked to rate their health status on the basis of their cardiac condition they found it difficult to make a general judgement in the presence of symptoms related to other chronic conditions. This may support the use of disease specific tools as advocated by some authors (Marks et al, 1992; Juniper et al, 1993). Thirdly, a small number of the subjects considered that some of the questions were irrelevant and as such they could not be answered because they referred to activities which they did not do. Generally the difficulties that subjects experienced in answering the SF-36 questionnaire as a measure of their health were related to the complexity of the notion of health itself as described in the literature (World Health Organisation, 1977; Pender, 1989; Neuman, 1989).

8.4.2 Changes in SF-36 scores between assessment at phases I and II

A comparison of the mean SF-36 scores at baseline and follow-up are given in table 6.7 and show statistically very significant improvements over every SF-36 domain, although approximately a quarter of the study group actually experienced a decrease in their follow up scores in any specific SF-36 domain. The pattern of change in SF-36-II scores varied across the eight health domains as outlined in table 6-9 with the largest improvement in follow-up scores observed in general health and physical

function and the greatest decrease in score observed for mental health. Role limitation due to physical factors and due to emotional factors changed least as a result of surgical intervention and may therefore be less useful as measures of health status. Although some workers report that generic health status measures may not be responsive to important clinical changes (Anderson, 1993), this did not appear to be a problem in the use of the SF-36 tool. The changes in scores before and after surgery support the view (Smith, 1981) that measuring health status is most useful when undertaken as a comparison at different time points rather than as an absolute state in itself.

8.4.3 Improvement and deterioration in SF-36 II scores

Although there was a diverse pattern of change in individual scores in each of the SF-36 II domains, the mean scores all improved. Increases of between 60% to 74% were documented in bodily pain, energy and vitality, social function and physical function which may reflect improvement in dimensions of health directly related to reduction or removal of angina chest pain which has been documented in other work to be correlated to perceived improvements in quality of life (Gortner et al, 1994). Largest reduction in health domain scores were of the order of 23% to 36% which is a smaller change than was noted in the scores that increased. The greatest reduction in score was in the mental health domain while the other areas were the same as the domain that showed the greatest increase.

More than half of the subjects did not change their scores in the role limitations due to physical or emotional factors. This pattern of change is different from that reported in a large study monitoring health status changes in patients with angina following introduction of additional nitrate therapy (Charlier et al, 1997). The pattern of change over the six month time period was that of a consistent increase over time, correlating with decrease in angina attacks, but of less magnitude (20-30%) than that observed in this work. In contrast to the results of this study, some of the largest increases were noted in the role limitation for both physical and emotional function.

This raises the issue of who improved their score between phases I and II and whose score deteriorated. Older subjects (with a later onset of CHD) and independently those with lower alcohol intake, higher social network score, non-smokers, absence of diabetes mellitus tended to show the greatest improvement as do those subjects with the lowest baseline SF-36 scores. The latter result is perhaps not surprising since these subjects had the greatest potential to improve. The literature supported these findings in relation to diabetes mellitus (Risum et al, 1996; Barbir et al, 1994). Other work examining the impact of smoking on outcome found no adverse effect at the time of surgery or shortly afterwards (Utley et al, 1996), but five years after surgery, smokers showed significantly higher mortality rates than non-smokers (Herlitz et al, 1997). This study, even with only moderate numbers of subjects, has shown that smoking status is a factor that adversely affects return of symptoms and lower health states at over a year after surgery.

Approximately 10% of the study cohort improved in every SF-36 domain, with improvement in six out of the eight domains the most likely outcome. The detailed results testing for statistically significant differences in the characteristics of the groups who had either improved, had the same or deteriorated SF-36 scores are presented in section 7.7. More in-depth analyses involving correlations and linear regressions have been undertaken using the SF-36 II score and angina II and breathlessness II self-rated scores as the dependent variables. These are discussed in section 8.5 and 8.6.

8.5 Correlations between SF-36 II domains and phase I variables

Correlation between SF-36 II domain scores and an extensive range of non-SF-36 baseline factors are presented in table 7.11. The correlations between SF-36 II and SF-36 I scores given in table 7.10 were so strong and statistical significant that they were examined using linear regression analyses. Although many of the correlations in table 7.10 were statistically significant for selected domains, it is the general trends, measured as a preponderance of either a positive or negative correlation coefficient that are perhaps most interesting. For example, each SF-36-II domain correlated negatively with alcohol intake, diabetes mellitus, deprivation category, number of CHD risk factors and current and past smoking status although only a few of these

pass the 95% confidence test applied in this work. The clear implication is that these factors were all detrimental to improvement in health after CABG surgery but taken individually, generally the effects were not statistically significant for the number of subjects recruited in this study. However, it seems likely that their statistical status would change if more data were available. It would then be possible to quantify their role with regard to the evolution of the SF-36-II domains after CABG surgery. By contrast, older subjects and those with high levels of social network support at phase I have positive, often statistically significant, correlations with all the SF-36-II domains.

8.6 Regression analysis SF-36-II

Linear regression analyses undertaken in a step-wise process have examined the contribution of phase I variables to SF-36 II scores. The statistically significant variables and directions (positive or negative) of their effect are displayed in table 8-2.

Table 8-2. Significant coefficients in the regression of SF-36-II domains with phase I variables

SF-36-II domains	Bodily Pain	Energy Vitality	General Health	Mental Health	Physical Function	Role: Emotional	Role: Physical	Social Function	Mean
Bodily pain	+ve								
Energy/ vitality		+ve	+ve						
Mental health				+ve	+ve	+ve			
Physical function					+ve				
Role: physical						+ve	+ve		
Social function								+ve	
SOC I	+ve	+ve	+ve	+ve	+ve		+ve	+ve	+ve
diabetes mellitus			-ve		-ve	-ve	-ve		-ve
current smoking I				-ve				-ve	-ve
past smoking I						-ve			
alcohol I		-ve		-ve					
age			+ve						
waist I					-ve				
weight I					+ve				

In table 8-2, a positive factor indicates a beneficial effect and tends to increased a score while a negative factor is detrimental and correspondingly tends to decrease a score. The percentage of the total variation in the SF-36 scores obtained at phase II assessment explained by the phase I variables ranged from 13.3% to 29.5%. The remaining variation in the scores may be attributed to unidentified factors and the random behaviour of the variables measured. In terms of interpretation of these percentages for a problem of such complex behaviour, the results can be viewed as providing a meaningful level of explanation of the contribution of a range of factors to the outcome measure being tested (Wonnacott and Wonnacott, 1981).

8.7 Major contributing factors to improved SF-36 II scores

8.7.1 SF-36 domains

For each domain of the SF-36 health scores obtained at phase II assessment the baseline level of the health domain contributed to the final value in all instances. This may be expected as an intrinsic characteristic of the measurement tool itself. Often other SF-36 domains contributed to the phase II value of other domains.

8.7.2 Social Network Scores

The general consensus arising from the regressions analyses was that social network score was the most important non-SF-36 factor contributing to health status at phase II as measured by the SF-36 score. It was significant in every regression except for role limitation due to emotional factors, a domain that is relatively unchanged in almost 50 percent of the cohort. At phases I and II the mean social network score for the study population was found to be respectively highly significantly ($p<0.001$) and very significantly ($p=0.004$) lower than the mean score for the population participating in the HIE (Donald and Ware, 1982). The scores for males and females were not statistically different ($p=0.395$). Confirmation of consistency of this measure was provided by a positive correlation of the social network score and the social function domain of the SF-36 measure.

The importance and positive consequences of social support have been documented in epidemiological studies (House et al, 1988; Berkman, 1995) in relation to extension of life span and in specifically to reduced risk of cardiovascular mortality (Kawachie et al, 1996; King et al, 1993). The results of this study strongly endorse the importance of high levels of social support to general health and well-being following CABG surgery. Interestingly, the factors that were found to be helpful in the recovery from surgery were related to 'lay support' which is a form of social support. Because social support as a dimension of health and well-being was lower than in other population groups (Donald and Ware, 1982) this factor may help to explain why the general health of subjects as measured by the SF-36 health questionnaire was also lower than other individuals with CHD and a general population group.

8.7.3 Diabetes Mellitus

The second most important phase I variable was diabetes mellitus, which contributed significantly to four of the SF-36 phase II domains and to the mean SF-36-II score. No statistically significant gender differences were detected in the presence of diabetes mellitus in the study subjects although other studies have related adverse outcome in females following CABG surgery to higher levels of diabetes mellitus (Barbir et al, 1994; Brandrup-Wognsen et al, 1995). Long term mortality in patients with diabetes mellitus following CABG surgery has been shown to be higher than in a non-diabetic patient group (Risum et al, 1996).

8.7.4 Smoking Status

The third most important variable was current and past smoking status which made a significant contribution to three SF-36-II domains and to the mean SF-36-II scores. Current smoking levels were 22.9% and 24.9% at phases I and II respectively in the total study group, wth no statistically significant gender difference. This level of smoking was more than double that noted in other studies (Utley et al, 1996) that have shown that there is an increased mortality in smokers compared to non-smokers at five years following surgery. Therefore in the longer term the study subjects with high levels of smoking were likely to be at increased risk of dying compared to other patient groups.

8.8 Minor contributing factors to SF-36 II scores

8.8.1 Age

Older age positively contributed to improved general health domain of the SF-36 score in this study group. In the interpretation of this result it should be noted that in this study group, the maximum age was 79 years which limits the extent to which older age of any value would continue to make a positive contribution to improved health status. In the literature both advanced age (Khan et al, 1992; Mick et al, 1991) and younger age (Wagner et al, 1996) have been associated with adverse outcome following CABG surgery.

8.8.2 Waist circumference

Increased waist circumference was common and a greater problem for females than males at both assessments ($p<0.001$). Increased waist circumference is a measure of abdominal obesity which has been shown to be related to higher rates of diabetes mellitus, and risk of CHD (Lean et al, 1998; Lean et al, 1995). There are no specific studies cited in the literature examining the impact of increased waist circumference to outcome following CABG surgery. Further work is required to examine the effect of this factor together with the impact of lifestyle interventions to reduce waist circumference and subsequent health outcome.

8.8.3 Body Mass Index

Body mass index exceeding ideal levels was common in the study group. When a BMI cut-off level of 30 was used as a criteria for obesity, approximately one quarter 22.9% (27.2%) of the study subjects had levels above this and the percentage of females statistically significantly higher than that males ($p=0.030$) at phase II. Obesity did not feature as a significant variable in terms of influencing health status following CABG surgery as measured by CHD symptoms or SF-36 questionnaire which confirms findings of in other work (Orth-Gomer and Johnson, 1987) although not all studies were in agreement (Prasad et al, 1991).

8.8.4 Alcohol intake

Alcohol consumption was a less important variable even although increased intake contributed positively to the value of two SF-36-II domains. Excess alcohol intake has been related to increased risk of CHD (George, 1983) although a moderate intake has been reported as having a beneficial influence against CHD (Friedman and Klatsky, 1993). It is not clear how the results should be interpreted in this study as it may be that those individuals who were most ill abstain from alcohol therefore no alcohol intake becomes associated with low health states rather than increased levels of alcohol intake promoting improved health status.

8.9 Multiple CHD risk factors

The mean levels of blood pressure, plasma cholesterol levels, BMI, waist circumference, smoking status and presence of diabetes mellitus for the study cohort

at baseline and follow-up assessments were presented in tables 5-4 and 6-2 together with comparisons of the mean levels of these CHD risk factors by gender. The presence of multiple CHD risk factors assessed during phases I and II were similar and are presented in tables 5-5 and 6-5 respectively.

Both SBP and DBP increased between the assessments, a fact that may be explained by the removal of angina medication which also has an anti-hypertensive effect, possibly masking an underlying elevated blood pressure. There were no statistically significant differences between the percentage of males and females with either SBP or DBP above defined action levels (Sever et al, 1993). Although hypertension has not been shown to be an independent predictor of mortality in the short term following CABG surgery (Herlitz et al, 1996), it has been associated with a more adverse profile of CHD risk factors and poorer quality of life after surgery (Sjoland et al, 1997). In the correlation analyses neither SBP or DBP were shown not to contribute significantly to presence or absence of CHD symptoms or health status as measured by the SF-36 score at follow-up assessment.

There was no statistical difference between males and females at phase I in terms of cholesterol action levels. However, 73.2% of women had plasma cholesterol levels above the desired action level at phase II and this was significantly higher than the level for males ($p=0.03$). In the correlation analyses, plasma cholesterol levels were not shown to contribute significantly to the presence or absence of CHD symptoms or health status as measured by the SF-36 score at follow-up assessment. Although there is little evidence to document the short-term effects of elevated lipid on CABG outcome, longer term studies ranging between two years and 10 years have shown clinically significant improvements in subsequent CHD events (Simvastatin Scandinavian Survival Study, 1994), and angiographic improvements in graft atherosclerosis (Blankenhorn et al, 1987 ; Daida et al, 1995) when elevated lipids are lowered.

The majority of patients had three 34.4% (31.6%) or four 28.6% (29.7%) modifiable CHD risk factors at phases I and II respectively. The profile of CHD risk factors ranged from the absence of CHD risk factors in 3.2% (3.2%) of the subjects through to the presence of all risk factors (five in all) in 4.2% (7.6%) of the subjects with

more females having an increased number of CHD risk factors compared to males although this difference was not statistically significant. Females were also more likely to be overweight at phase II. The percentage of subjects with a greater number of CHD risk factors increased between the two assessments. These figures support the finding of other studies that have evaluated the presence of uncorrected CHD risk factors in CHD patients and patients following CABG surgery (Alderman, 1996; Lindsay et al, 1995; ASPIRE Steering Group, 1996) and highlights the scope for improved management of patients in order to address these correctable CHD risk factors, a process that other studies have demonstrated does reduce the risk of further CHD events in patients with established disease (Wong et al, 1989; Scandinavian Simvastatin Survival Study Group, 1994; Utley et al. 1996).

8.10 Health locus of control

A higher HLOC score (external HLOC) was negatively correlated with all the SF-36-II domains except for mental health and role limitation due to emotional factors. The literature has presented conflicting results for the relationship between internal and external HLOC with improved health-related behaviours and general health and well-being (Norman, 1995; Steptoe et al, 1994; Alderman et al, 1993). The theory does suggest that individuals with external HLOC belief are less likely to take action to improve their health (Younger et al, 1995; Weiss and Larsen, 1990) and the correlation of external HLOC with reduced levels of health as indicated above adds support to this theory. However, the correlation coefficients for HLOC were on average, lower that those for the social networks score, thus indicating that HLOC was a less important predictor of SF-36-II scores than social network score. The relationship of socio-economic deprivation class and health locus of control influencing health behaviour was examined. The two factors were not correlated in this group and it would appear that the two factors act independently of each other in terms of their relationship to health behaviours. This may be a reflection on the bias towards a greater number of subjects having higher levels of socio-economic deprivation.

8.11 Cardiac rehabilitation

The majority of patients attended and completed a cardiac rehabilitation programme (65%), with 10.4% of the subjects attending for part of the programme. This uptake rate was higher than reported in another study conducted in the same geographical area (Pell et al, 1996). Approximately one quarter of the subjects did not attend cardiac rehabilitation, because they had not been invited, that they did not like the programmes, that they could not do the exercises, that they had transportation difficulties or health problems. The two main themes that were identified from the responses relating to positive attributes of cardiac rehabilitation were *common sharing* and *confidence building*. These findings add support to group classes for cardiac rehabilitation as opposed to home-based programmes only since many of the positive effects are related to the safety and guidance from staff and the support from others dealing with similar health issues. The negative attributes related to the *nature of the exercises* and *transport*. Details of the responses relating to the positive and negative aspects of cardiac rehabilitation are presented in section 6.7.

There were no statistical differences in the presence of CHD risk factors between full attendees and non-attendees ($p=0.25$) or between full attendees and partial attendees ($p=0.17$) or non-attendees and partial attendees ($p=0.18$). However, cardiac rehabilitation provides a comprehensive multifactorial approach to support recovery and for many of the uncorrected CHD risk factors noted such as hypertension and elevated plasma cholesterol levels medical management has a lead role. It has been suggested that CHD risk factor management could be improved with improved communication and continuity of care for patients across both the Primary and Secondary care interface but also between the different professional providing care for patients following CABG surgery (Lindsay, 1995). There was no difference in presence of angina or breathlessness symptoms or when present the degree of severity in those whom attended, partially attended or did not attend. Therefore the presence or severity of CHD symptoms following CABG surgery was not a factor in determining attendance for the subjects in the study.

There were improvements in the health status as measured by the SF-36 questionnaire in those subjects who attended a full cardiac rehabilitation programme

when compared to non-attendees. The differences in mean scores are presented in table 6-10, and show that there were highly significant improvements in the general health domain and significant improvements in physical function, role limitation: physical and social function domains. This was a very encouraging finding, given the debate surrounding the efficacy of cardiac rehabilitation (Pell, 1997), although it is not clear form these results if the uptake of cardiac rehabilitation was higher in those subjects with higher levels of health at the outset.

These results must be interpreted with caution because the study was observational in design. There may be the possibility that the group who attended the cardiac rehabilitation and those who either partially attended or did not attend at all had different characteristics that may explain the observed difference in health status. Other research has shown that individuals from areas of high socio-economic deprivation are less likely to attend cardiac rehabilitation programmes (Morrison et al, 1997; Harlan, Sandler, Lee, Lam and Mark, 1995). Furthermore, in this study individuals from areas of high socio-economic deprivation were shown to have lower levels of health therefore deprivation category may explain the observed difference in health status between attendance and non-attendance at cardiac rehabilitation. To determine if this explained subjects pattern of attendance at cardiac rehabilitation in this study, the three attendance categories, fully attended, partially attended or non-attended, were correlated with deprivation category (Mann-Whitney U test). No statistically significant differences ($p=0.104$, $p=0.977$, $p=0.235$) across the three groups for the subjects' deprivation category were noted and therefore the observed differences in health status cannot be explained by differences in deprivation category. There may very well be other differences in the group which help to explain the changes in health status other than the impact of cardiac rehabilitation programmes.

8.12 Subjects' perceptions of health and experience of CABG surgery

8.12.1 General perceptions of health

In general, the comments relating to health covered a broad range of issues relating to many dimensions of health. Living with CHD was reported as having an all

pervading effect on health. The key issues relating to their health experience were captured within two main themes namely; *dependency* and *impending doom.* The detailed comments from the subject interviews are presented in section 5.10.

Dependency was the most common theme to emerge from analysis of all the responses with three sub-themes identified namely; *dependency on functional status*, *dependency on others* and *dependency on medication.* Dependency on functional capability was the most frequently raised issue by subjects in the study and different strategies in dealing with its limitations were described. Many subjects reported that they were not free to make choices about even very basic everyday activities such as visiting a friend or doing housework. Assessment of their health in terms of the level of cardiac symptoms and general tiredness was carried out frequently because capacity to cope with activity varied considerably and was unpredictable in advance. Some subjects found it difficult to express in broad terms a view of their health and well-being because of this changeability. A strategy was employed of undertaking activities in a graduai manner. Many subjects reported a high level of functional disability. Forward planning particularly of journeys that involved walking was a strategy employed by a number of the subjects. These expressions of dealing with the health implications of CHD are similar to those described in other illnesses in terms of the need to adapt and change in order to cope (Matson, 1977), a process that has been described as similar to that of a grieving process.

Fragility surrounding their very existence was a real concern that was strongly apparent in subjects' accounts. A sense of fear that the operation date would be too late and that their heart condition would suddenly deteriorate was apparent in these responses. This affected their ability to undertake basic everyday activities in case something dreadful happened to them. An insight into the anxiety and burden of living with CHD was provided which was acknowledged to be more troublesome because of the long wait for CABG surgery.

8.12.2 Expectations of benefit from CABG surgery from the patient perspective

It became obvious that many subjects were unclear on the effect that surgery would have on their health. It was a matter that was not readily discussed with family

members who were also worried about their health and well-being. Others were clear that the surgery was necessary if their health was not going to deteriorate further if not a life-saver in itself. The main themes that emerged from analysis of the interviews were '*freedom and independence*'; '*hope, chance, uncertainty*' and '*years to life, life to years*'.

The expectations reflected a desire to be relieved of the enforced dependency as a result of angina symptoms that was viewed as a negative effect on perceived health. The impact of angina symptoms on unrealised benefit in quality of life following CABG surgery was a finding in a study examining the relationship of expected to realised outcomes (Gortner et al, 1994).

Many subjects viewed the outcome of CABG as uncertain with apprehension about their future health being reported. Uncertainty of expected outcome has been highlighted in other work (Staniszewska and Ahemed, 1998) investigating patient expectations and satisfaction with health care which found that expectations were a varying phenomenon, ranging in content, strength and whether patients attached value to them. The study also reported that patients took their expectations into account when they evaluated care.

In a study interviewing patients prior to angioplasty it was shown that despite all patients discussing the risks of the procedure with the Consultant, 63% of the patients had not accurately assimilated risks and benefits of the various treatment options (Kee et al, 1997). Uncertainty related to risk of an adverse or undesirable outcome has been highlighted as a factor that can increase confusion in understanding (Calman, 1996). In order to address this issue it has been suggested that a classification system should be developed to improve understanding of the processes involved and the size of the risk including concepts such as avoidability, justifiability and seriousness (Chief Medical Officer, 1995; Chalmers, 1995).

In their comments related to expectation of health benefit from surgery, subjects drew a distinction between extension to life span and that of quality of life. Quality of life improvement was an expectation of many of the subjects although what this meant in detail was not explored. Some subjects related improved quality of life to enhanced

functional status as a result of relief of symptoms while others expressed a more ethereal desire to generally feel better within. These contrasting views of quality of life are similar to those that have been documented by others (Spitzer, 1987; Harrison et al, 1996). The view that the operation would confer additional life expectancy, with a specified time period cited, was a common expectation with no reference to changes in symptoms, functional status or general health and well-being although this may be assumed to be part of the extension to life. In this study no attempt has been made to examine the relationship between expectations and outcome from surgery.

Kee (1996) has suggested that further research can be justified to examine the relationship between patient expectations and health outcome in order that preparation and education of patients prior to interventions could be provided in a more appropriate manner.

8.12.3 The CABG Surgery Experience

There was a range of comments relating to the general experience of undergoing CABG surgery with a perspective focusing on the effect on health status rather than the experience itself. Two main themes were identified in the accounts of the surgical experience: that of '*the importance of lay support*' and '*the enormity of the experience*'. The responses collected as 'memos' during the interviews presented a rich picture of the experience and are presented in section 6.3 and provide an important patient perspective on what the process of undergoing CABG surgery was like. The comments that were collected in relation to the experience of CABG surgery were varied but as a general impression was given that the operation presented a much greater challenge than was expected. Evidence of coping and support strategies were provided as the subjects dealt with this new and demanding event which was in common with views expressed by other cardiac patients during the recovery process (Jaarsma et al, 1995).

8.12.4 Health status following CABG surgery

A range of comments was given in response to the enquiry about health status following surgery. Many of the comments on health status post-surgery were based on the same areas of concern that had been raised at the pre-surgical interview. From

an analysis of these comments, two broad themes were identified namely: *removal of a death sentence* and *freedom of choice.* The detailed comments are presented in section 6.9. Many subjects evaluated the benefit of having the surgery as a strategy to secure their future health with the threat of a sudden problem arising with their heart with likely dire consequences. The life/death dichotomy that was being described prior to surgery was viewed as being resolved. For some the operation was viewed as a reprieve from death while for others it was to have their life revitalised. These views appeared to address the pre-operative concern described as 'impending doom' that had been a theme in the pre-operative accounts of health status.

The views and insights provided a picture of CABG surgery being regarded as a significant major life event and perhaps more information, advice and counselling would be helpful to support patients before, during and after surgery. Although quality of life improvement was an expectation raised before surgery it did not feature strongly in the accounts of health after surgery. Health was related to a sense of freedom and removal of the need to be dependent on others. These accounts are congruous with the idea that quality of life as an entity is related to a person's expectations of what 'normality' means (Harrison et al, 1996). The influence of surgery on health was perceived by many in terms of the freedom to be able to undertake activities that they wanted to do an example of one such without the need for forward planning that had been necessary before surgery.

In another study the major processes that individuals engaged in following CABG surgery in seeking normality have been described in three conceptual stages; surviving, restoring and being fixed (Keller, 1991). These stages were reflected in this study as they are closely related to the themes that emerged from the interviews following CABG surgery; specifically removal of a death sentence, being a new person and rejuvenation. Many study subjects highlighted the importance of removal or reduction in the limiting symptoms of angina and breathlessness and the resultant improvement in their basic mobility. This supports results from other studies that related reduced quality of life with continued angina in patients following CABG surgery (Pocock et al, 1996). In a study examining the patients' perspective on outcome following CABG surgery (King, 1992), patients who believed surgery was

worth it because of functional improvement had more positive scores on subjective indicators of life satisfaction and mood than those believing surgery was worth it because it saved them from death or those who were not sure surgery had been worth the effort. The relationship between improved functional status and quality of life was reflected also in the subject accounts in this study.

8.13 General Conclusions

The health status of subjects prior to and following CABG surgery was assessed in this study. An examination of different measures of health through data triangulation provided details of the interactions and inter-relationships between cardiac related symptoms, CHD risk factors with multi-dimensional measures of health and psycho-socio-economic determinants of health. Detailed conclusions of the results are presented at the end of each of the three result chapters. The main conclusions of the work undertaken in this thesis are outlined below.

- Operative mortality rates (4.8%) and one year survival rates (93.08%) were similar to other national and international centres.

- Relief of angina and breathlessness symptoms was achieved in more than half of the subjects. Those patients with higher levels of angina or breathlessness symptoms at follow-up assessment were more likely to have diabetes mellitus, be a current or past smokers and/or have higher level of symptoms prior to surgery and have lower than average health states as measured by the SF-36 domains.

- Health status, as measured by the SF-36 protocol, was lower than other patient groups with CHD prior to surgery and lower than a large general population sample at a mean of 16.4 months after surgery. It was lower in subjects from areas of high socio-economic deprivation.

- Mean SF-36 domain scores were statistically significantly improved after surgery with three-quarters of all subjects increasing their scores. Approximately 10% of the subjects improved in every SF-36 domain. Those who made the biggest

improvement tended to have the lowest SF-36-I scores and hence the greatest potential to improve their scores, and also tended to be older at the onset of CHD.

- Improvement in six out of eight domains was the most likely outcome. Higher levels of angina and breathlessness before surgery were associated with lower SF-36 scores, i.e. poorer health, and were also associated with less improvement in SF-36 scores at follow-up.

- A strong social network, as measured in the study, was associated with improved health status.

- The presence of multiple CHD risk factors assessed during phases I and II were similar, with the majority of subjects having three or four modifiable CHD risk factors. The study has highlighted the scope for improved secondary prevention care in the management of such patients in order to address these correctable CHD risk factors.

- This study has generated detailed assessment of the symptomatic and general health status benefits of a group of individuals with CHD undergoing CABG surgery. The results add to the existing knowledge documented in the literature through the provision of detailed analysis of the interaction of a large range of patient variables resulting in the generation of contemporary data on symptomatic relief and morbidity effects of CABG surgery.

- Confirmation of the major determinants of adverse outcome such as the presence of diabetes mellitus and younger age was made.

- The strong positive effect of social networks on outcome has not been previously documented in such a patient group.

- The expectations of benefit from surgery were varied and immense and echoed expectation reported in a small study of elderly patients (Gortner, 1994) although the diversity of expectations which in some cases may not be realistic have not been reported elsewhere.

8.14 Generalisability of Results

Generalisability is the extent to which the results of a study undertaken in a sample of a population can be applied to the population as a whole (Polit and Hungler, 1996). In order to address this issue it is necessary to be able to demonstrate that the characteristics of the sample studied are representative of the population from which they were selected. The population may be considered at different levels. It is primarily the population of all patients undergoing CABG surgery at the study centre and in order to demonstrate that no bias was introduced in the selection of the sample from the total population the main characteristics of the sample group and population should be similar. In order to be able to demonstrate wider generalisability it is necessary to demonstrate that the procedure undertaken and the patient characteristics are similar to that undertaken in other defined groups. The inclusion and exclusion criteria used to select the sample i.e. first operation, single procedure and elective surgery defines the main surgical differences in patient selection for CABG surgery in this study and therefore the population of CABG operations to which the results of this study may be applied. Comparison of the age and gender of the study subjects to that of three other patient groups has been undertaken namely:- comparison with the population of patients undergoing surgery at the study centre from which the sample were identified, patients undergoing CABG surgery in the GGHB area and national statistics for cardiac surgery in section 5.2. The main subject characteristics assessed were age, gender and socio-economic deprivation status. The study subjects were younger than all the comparative groups had the same gender ratio and were from areas of higher socio-economic deprivation than the GGHB patients (data only available for this group). It was not possible to assess other patient variables such as severity of disease, involvement of the LAD coronary artery, LVF which characterise a higher risk group of individuals undergoing surgery. Therefore comparison of the study cohort with that of other operative series must be undertaken with caution because of the large number of variables that are not explicitly provided and that influence the outcome of the procedure.

It could be argued that as the study group came from the West of Scotland, where CHD rates are much higher than elsewhere in the country, that this group may be either more sick or atypical of all patients undergoing CABG surgery. In terms of

presence of CHD risk factors detailed assessment does not support this. In fact, when compared to the ASPIRE study (ASPIRE Steering Group, 1996), where centres across the UK were examined in terms of the prevalence of uncorrected risk factors in patients with CHD, it found that there were similar rates across all the centres. In addition, the peri-operative mortality rate was similar to that reported in other centres, both in the UK and in the USA.

8.15 Study Limitations

In any study it is important to consider potential limitations in terms of patient selection, methodology, interpretation of results and the conclusions reached.

8.15.1 Observer Influences and Bias

The collection of the data set in this study necessitated close clinical contact between the researcher and the patient. It could be argued that such interactions in themselves could influence the patients' outcome. However, as previously stated in the methods section, the interviews were conducted in as passive a form as would be ethically permissible and no effort, other than standard lifestyle advice on body weight, smoking and exercise patterns was provided.

The researcher was extremely careful in the conduct of the interviews to avoid influencing the patients in terms of their health perceptions or expectations about their forthcoming surgery. Full transcripts from the taped interviews may have provided a fuller picture of the patients' health, however, the method that was chosen, that of memo taking, is a recognised technique, particularly for use in large subject groups. The problem of observer subjectivity in this technique was minimised by the fact that there was only a single researcher (the author) involved in conducting the interviews and recording the memos on the basis of the subjects' response to the questions outlined.

8.15.2 Multiple Statistical Hypotheses Testing

The p-values were set for a significance level of 0.05 and were not adjusted to take account for errors arising through the process of multiple comparisons. The limitations are outlined in section 4.19.11 and advise that any borderline p-values

were interpreted with caution. However, the main parameters that were shown to be highly significantly correlated had p-values of 0.001 or less and therefore it is less likely that the problem of multiple comparisons will change the interpretation of these results.

8.15.3 Assessment of CHD Symptoms

Symptoms of angina were assessed using two single item scales for angina, chest pain and breathlessness as previously described. Characteristics of the symptom of angina were not documented, specifically site of pain, radiation beyond chest to arm, the character of the pain in terms of duration and frequency or in relation to exertion or stress or use of GTN spray. Therefore the symptoms of angina and breathlessness are governed by the patient's interpretation of chest pain, angina and breathlessness and do not represent a detailed description of myocardial ischaemic pain. However, for practical purposes it is the patient's interpretation of pain in the first place that is used as an indicator of clinical severity and subsequent management and as such is an important perspective in clinical practice.

8.15.4 The SF-36 Health Questionnaire

The number of patients studied was based on a power calculation for the main health status measure SF-36. While this has not been previously used in CABG surgical patients, it has been used by patients with angina and post MI, and other surgical patients. Three general issues arose that posed difficulty for some subjects answering the questions. These were identified as the dependency on other variables, symptoms related to other chronic condition and irrelevant questions. The specific comments relating to each theme are outlined in the following sections 8.15.5-8.15.7.

8.15.5 SF-36 Dependency on other variables

Many subjects experienced some difficulty in selecting an appropriate response to a question because, within the time frame that the question referred (4 weeks), they considered that their health status fluctuated as illustrated by one subject '*the questions don't take into account the day to day variability, even at different times during the day affects how you feel*'. Others reported that their general health status was dependent on specific conditions, for example '*how I feel depends on if it is*

after food and what the weather is like'. Many subjects reported increase in angina symptoms after a heavy meal and in cold and windy weather conditions. Specific areas that influenced their general feeling of well-being were related to physical activity if they were exerting themselves too much or able to undertake activities at a leisurely pace had a great impact. For example, one subject noted that '*the distance that I can walk depends on resting every 30 to 40 yards, but I can walk quite a long distance beyond that'* and another subject commented that *'walking depends on whether there are hills, I can walk for miles along the flat'*. The questions within the SF-36 form which assess the distance that a respondent can walk as a measure of physical function are based only on different distances and doesn't take into account the time taken to cover the set distances or if the there are inclines or level areas.

The time interval between taking cardiac medication and making an assessment of their health status influenced the way in which they responded to some of the questions. Similarly if subjects had pain, then issues such as whether or not they had taken analgesics and, the timing relative to completing the questionnaire influenced the response choice. One subject said that many of the response choices that they made were dramatically influenced by the fact that they had been told that they needed heart surgery. This had been very unexpected information.

8.15.6 SF-36 Responses related to other chronic conditions.

Several subjects had other medical conditions, in addition to CHD. Arthritis was common and a minority reported that they felt depressed or that they felt preoccupied. The function of the SF-36 questionnaire was to generate a general overall measure of health and the presence of other illness should not be a problem in its use. A small number of the subjects had made the assumption that the questions should be answered in relation to the effects on their health as a result of CHD and were not sure if they should ignore the effects of other conditions when completing the questions. The importance of noting the presence of other medical conditions that influence health status became apparent in the interpretation of the results.

8.15.7 SF-36 Irrelevant questions

A small number of the subjects considered that some of the questions could not be answered because they referred to activities that they didn't participate in, for example, '*don't do any vigorous activity*'. Similarly the question of degree of bodily pain was considered irrelevant to one subject who commented '*I have no pain, but breathlessness at any physical effort is a big problem'*. The comment from one unimpressed subject, '*I thought that the questionnaire was stupid and vague'* suggests that the questions did not appear to be considered either relevant or sufficiently specific to be seriously considered as a health measure.

8.15.8 Health Locus of Control

The concept and implications of health locus of control remains controversial and the scale utilised within this study has not been widely validated. However, it was chosen for use in this study because the Glasgow centre for the WHO MONICA study has used this scale in a large number of the general population and as such, has a data set that was useful for comparison to the population in this study. This only provided information in terms of the scale's ability to measure different levels of health locus of control between individuals and does not make any comment in relation to health locus of control as an entity, if indeed such a concept does exist.

8.15.9 Other Major Changes Influencing Health Status

Underpinning the whole study was the assumption that changes from baseline assessment, both positive and negative, were as a result of the intervening CABG surgery. Obviously, other major life events may have taken place in the months between assessments, for example, death of a spouse or major concomitant illness. Such events however, were taken account of and recorded in the interviews at follow-up, and although not directly used in the analysis they did form a perspective of the patients' general health status as reported by the subjects themselves. In a sample of over 200 patients it has been assumed that the number of life events would be similar to that of an age and gender match population sample. Six of the subjects had been prescribed medication for either anxiety or depression. Although depression was not formally assessed, either at baseline or at follow-up assessment in this study, the SF-36 health domain of mental health does address emotional problems as a dimension

of health. In further studies, this effect could usefully be evaluated using specific instruments such as the Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) or the Beck Depression Index (Beck and Beck, 1972). The major strength of the study lies in the fact that paired measurements have been undertaken at baseline and follow-up in the same individuals. This allows intra-individual comparisons to be made, thereby removing the potential error in data collection that arises when different groups of patients or subjects are measured over time.

Both males and females were included in the study and the ratio of males to females was similar to that in other groups of patients undergoing CABG surgery. Multiple instruments were used in order to assess health status from a variety of perspectives and this can only strengthen the weakness that may be inherent in the use of any individual instruments.

As already commented earlier, many correlation between SF-36 and non-SF-36 variables were all single signed but not strong enough to reach the 95% confidence level and this included plasma cholesterol and age.

8.15.10 Subject sub-groups

The number of subjects in the study was not large enough, however, to make meaningful conclusions in several interesting sub-groups. Interesting differences have been noted between the males and females, for example more severe angina symptoms, higher levels of socio-economic deprivation, however, a larger study in women alone would be required to examine the implication of these findings to health outcome following CABG surgery. It was also not possible to analyse statistically the characteristics of those subjects who have no angina or breathlessness symptoms at phase I of the study or those subjects who died during or shortly after CABG surgery. For the study group as a whole it was only possible to identify dominant variables because of small number of subjects in particular sub-groups.

8.16 Recommendations

The study has highlighted that the health status and symptomatic status of patients on

the waiting list for bypass surgery is far from ideal with low levels of health and high levels of symptoms reported. In addition, many of the known CHD risk factors such as smoking, obesity, hypertension, hypercholesterolaemia, lack of exercise, are not uncommon in such patients. The time on the waiting list would provide the ideal opportunity to focus and concentrate efforts in modifying such factors. The data collected and results generated during this study underline how import it is that health care policy makers and clinicians increase their efforts to reduce waiting lists for CABG surgery.

A variety of expectations from CABG surgery were reported by the patients, highlighting factual inaccuracies and a lack of understanding as to the possible benefits that the surgery might offer. A significant number of the subjects were not well informed about the surgery itself and its expected outcome and many based their experience and understanding on those of friends, family or individuals in the media. More structured information on likely benefits could help to address this issue. It is recognised that the medical literature describes outcome in complex language and it is difficult to interpret outcome benefits from large groups to individual patients. In general, patients had a simplistic view of what the surgery could offer, which may indeed increase anxiety levels.

Symptomatic assessment of angina and breathlessness using a rating scale proved to be a useful outcome measure. It was able to discriminate between different patients in terms of the level of symptoms in a more sensitive way than the NYHA grading which divided subjects between the two middle grades of symptoms only. Further work requires to be done to validate such scales in larger groups of patients, comparing it to other measures of clinical symptomatic severity.

Patients were able to recall accurately the level of pre-operative symptoms at their post-operative assessment more than a year after surgery. Therefore, post-operative assessment of change in symptom severity, as described by the patient, could be used as a useful outcome indicator for use in routine practice and will provide a more sensitive measure of benefit of surgery rather than the hard statistics of mortality.

Patients with the most severe levels of angina and breathlessness prior to surgery had the least improvement in symptoms afterwards. Further investigation of the selection of patients with symptomatic CHD in terms of both medical management and timing of surgery may help improve our understanding of the optimal timing and appropriateness of CABG surgery for individual patients. In particular, there was least improvement in breathlessness symptoms following surgery, which was correlated with high levels of breathlessness prior to surgery. It is recommended that more detailed investigation be conducted into the possible causes of breathlessness e.g chronic obstructive airways disease, emphysema and other respiratory complaints using pulmonary function tests. These were beyond the scope of this thesis. People in general were good judges of their own symptoms and the anecdotal experiences of living with CHD and the experience of having surgery provided an in-depth and sensitive view of the impact of CABG surgery on both individuals and their families.

Symptoms of anxiety and depression were not examined in detail in these studies. Indications from the mental health domain of the SF-36 measure and subjects' own accounts of health suggest that these problems may be unrecognised or under-estimated in these patients. Clinicians should be sensitive to these issues. The patients reported the benefits of support from other patients during their hospital stay as an important source of help and encouragement. Such findings would suggest that patients should not be moved unnecessarily to different accommodation for non-clinical reasons. Uptake of cardiac rehabilitation was high in this cohort and patients were usually enthusiastic about the benefits that such programmes offer. The efficacy of a modified cardiac rehabilitation programme during the waiting time for surgery would be a recommendation for further work to improve care of patients undergoing CABG surgery. This study was unable to examine long term outcome in the subjects because of time constraints. Since such detailed in-depth information has now been collected and has characterised many dimensions of health status before and after CABG surgery, this would provide a unique data set in order to examine intermediate and long term outcome and the effect of pre-operative status.

8.17 Full Circle

The study began with the recognition the patients undergoing CABG surgery had uncorrected CHD risk factors that were likely to have a detrimental effect of the

benefit of surgery to health and well-being. The work undertaken in this thesis examined in greater detail wider aspects of the health status of patients prior to surgery and then following surgery.

The findings reveal that patients undergoing CABG surgery still have uncorrected CHD risk factors and that, although they were not found to be major determinants of improved health status after surgery, they are likely to be detrimental in the long term. Health status measured using a range of variables was undertaken within the study in an attempt to identify a means of measuring benefits to health following surgery and to provide an insight into factors that were associated with health outcome. The study results have confirmed that a range of factors relating to aspects of health and well-being before surgery were associated with health status following CABG surgery. Many of these factors could be improved prior to surgery. In addition such factors that have been shown to have an impact on health outcome could be used to develop improved criteria for patient selection.

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Appendix I. Ethical Approval

Royal Infirmary
of Castle Street
Glasgow G4 0SF

Telephone 041 552 3535
Fax 041 304 4889

Research Ethics Committee

Chairman: Mr Colin Buck
Secretary: Mr Iain Douglas, Administration

Our Ref:DB/555
(Please quote on
all correspondence)

If Phoning Ask For:
Sharon - ext 4020

10th April 1995

Professor D J Wheatley
Cardiology
GRI

Dear Professor Wheatley,

Research Ethics Committee - Submission:

The impact of healthy lifestyle on one year outcome following coronary surgery

I am now pleased to advise you that, at the April meeting of the Research Ethics Committee, this project was approved. The Patient Information and Consent form and any protocols submitted with the project have also been approved.

The study must be undertaken within two years of the date of this letter. After that time approval will be deemed to have lapsed and the project will require to be resubmitted. Please note that approval is conditional upon a report being submitted to the Research Ethics Committee. For this purpose, a pro-forma questionnaire will be forwarded to you in approximately one years time.

Trust Board approval is also given, as there are no substantial financial implications. I should be grateful if you would ensure that relevant senior nursing staff are informed about the study when in-patients are involved.

You may therefore take it that the application has been approved on behalf of the Research Ethics Committee and the Trust Board and you may proceed.

Yours sincerely,

pp

Iain Douglas
Secretary

DATE 12/4/95.
RECEIVED:
DEPT OF SURGERY

Appendix II. Patient information letter and written informed consent

FORM 3 GLASGOW ROYAL INFIRMARY UNIVERSITY N. H. S. TRUST RESEARCH ETHICS COMMITTEE

COMPLETION OF THE PATIENT INFORMATION AND CONSENT FORM

Title of Project:

The impact of healthy lifestyle on one year outcome following coronary surgery

Patient Information and Consent Form

I understand that Grace Lindsay, a Research Nurse is conducting a study, under the supervision of Professor Wheatley, Professor Smith and Dr Hanlon to assess the influence of general health and lifestyle on success of coronary artery bypass surgery. Taking part may be of little or no benefit to me but the results may help other patients in the future. The study involves the following:

1. A visit to the hospital before the date for your surgery and at one year after surgery.
2. The completion of a self-administered questionnaire on your diet
3. Measurement of height, weight, waist, hip size and blood pressure

4. A standard blood (10ml) sample for measurement of blood fat levels

5. Answering a questionnaire relating to your general health, your ability to cope with day-to-day activities and the severity of your angina symptoms

At any time you wish to stop taking part you may do so. The care which you are presently receiving will not be affected in any way.

Your General Practitioner will given information about any care which you receive.

CONSENT

I, (Name)..... of (Address).....

.....

agree to take part in the Research Project/Study Programme described above.

Dr/Mr ..... has explained to me what I have to do, how it might affect me and the purpose of the Research Project/Study Programme.

Signed: ..... Date: .....

Witness: ..... Date: .....

Appendix III. Short-form 36 Questionnaire

The Short Form 36 (SF-36) Health Survey Questionnaire

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions, please give the best answer you can and make any of your own comments if you like.

1. In general would you say your health is:

(Please tick one)

- Excellent ❑
- Very good ❑
- Good ❑
- Fair ❑
- Poor ❑

2. Compared to a ***year ago,*** how would you rate your health in general now*?*

- Much better than a year ago ❑
- Somewhat better than a year ago ❑
- About the same ❑
- Somewhat worse than one year ago ❑
- Much worse now than one year ago ❑

3. **Health and Daily Activities**

The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, by how much?

(Please tick one box on each line)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	❑	❑	❑
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	❑	❑	❑
c) Lifting or carrying groceries	❑	❑	❑
d) Climbing several flights of stairs	❑	❑	❑
e) Climbing one flight of stairs	❑	❑	❑
f) Bending, kneeling or stooping	❑	❑	❑
g) Walking more than a mile	❑	❑	❑
h) Walking half a mile	❑	❑	❑
I) Walking 100 yards	❑	❑	❑
j) Bathing and dressing yourself	❑	❑	❑

4. . During the past ***four weeks***, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? (Please answer Yes or No to each question)

		Yes	**No**
a)	Cut down on the amount of time spent on work or other activities	❑	❑
b)	Accomplished less than you would have liked	❑	❑
c)	Were limited in the kind of work or other activities	❑	❑
d)	Had difficulty performing the work or other activities (e.g. it took extra effort)	❑	❑

5. During the past ***four weeks***, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please answer Yes or No to each question)

		Yes	No
a)	Cut down on the amount of time spent on work or other activities	❑	❑
b)	Accomplished less than you would have liked	❑	❑
c)	Didn't do work or other activities as carefully as usual	❑	❑

6. During the past ***four weeks***, to what extent has your physical health or emotional problems interfered with your normal social activities with the family, friends or groups?
(Please tick one)

- Not at all ❑
- Slightly ❑
- Moderately ❑
- Quite a bit ❑
- Extremely ❑

7. How much bodily pain have you had during the past four weeks?

- None ❑
- Very Mild ❑
- Mild ❑
- Moderate ❑
- Severe ❑
- Very severe ❑

8. During the past ***four weeks***, how much did pain interfere with your normal work (including work both outside the home and housework)?

- Not at all ❑
- Slightly ❑
- Moderately ❑
- Quite a bit ❑
- Extremely ❑

These questions are about how you feel and how things have been with you **during the past month**. (For each question, please indicate the one answer that comes closest to the way you have been feeling).

9. How much time during **the past month:** (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
a) Did you feel full of life?	❑	❑	❑	❑	❑	❑
b) Have you been a very nervous person?	❑	❑	❑	❑	❑	❑
c)Have you felt so down in the dumps that nothing could cheer you up?	❑	❑	❑	❑	❑	❑
d) Have you felt calm and peaceful?	❑	❑	❑	❑	❑	❑
e) Did you have a lot of energy?	❑	❑	❑	❑	❑	❑
f) Have you felt downhearted and low?	❑	❑	❑	❑	❑	❑
g) Did you feel worn out?	❑	❑	❑	❑	❑	❑
h) Have you been a happy person?	❑	❑	❑	❑	❑	❑
I) Did you feel tired?	❑	❑	❑	❑	❑	❑
j) Has your **health limited your social activities** (like visiting friends or close relatives)?	❑	❑	❑	❑	❑	❑

10. Please choose the answer that best describes how true or false each of the following statements is for you.

(Please tick one box on each line)

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a) I seem to get ill more easily than other people	❑	❑	❑	❑	❑
b) I am as healthy as anyone I know	❑	❑	❑	❑	❑
c) I expect my health to get worse	❑	❑	❑	❑	❑
d) My health is excellent	❑	❑	❑	❑	❑

Calculation of SF-36 health domain scores

Physical function (PF)

PF = 3a + 3b + 3c + 3d + 3e + 3f + 3g + 3h + 3I + 3j
Physical function score = ((PF-10)/20) * 100

Role limitation due to physical problems (RP)

RP = 4a + 4b + 4c + 4d
Role limitation due to physical problems score = (RP/4) * 100

Role limitation due to emotional problems (RE)

RE = 5a + 5b + 5c
Role limitations due to emotional problems score = (RE/3) * 100

Social functioning (SF)

SF = 6 + 9j
Social functioning score = ((SF-2)/9) * 100

Mental health (MH)

MH = 9b + 9c + 9d + 9f + 9h
Mental health score = ((MH-5)/25) * 100

Energy/vitality (EV)

EV = 9a + 9e + 9g + 9i
Energy/vitality score = ((EV-4)/20) * 100

Pain (P)

P = 7 + 8
Pain = ((P-2)/9) * 100

General health Perception (GHP)

GHP = 1 + 10a + 10b + 10c + 10d
General health perceptions = ((GHP-5)/20) * 100

Change in health (CH)

CH = 2
Change in health score = ((CH-1)/4) * 100

Appendix IV. Health Locus of Control

Health Locus of Control

Adapted from : Wallston BS, Wallston KA, Kaplan GD, and Maides SA (1976) Development and validation of the Health Locus of Control (HLC) Scale. Journal of Consulting and Clinical Psychology 44:580-585.
Please tick a single box to answer each question

	Strongly agree	Agree	Disagree	Strongly disagree
I* 1. If I take care of myself, I can avoid illness	❑	❑	❑	❑
I 2. Whenever I get sick it is because of some-thing or not I've done	❑	❑	❑	❑
E* 3.Good health is largely a matter of good fortune	❑	❑	❑	❑
E 4. No matter what I do, if I am going to get sick	❑	❑	❑	❑
E 5. Most people do not realise the extent to which their illnesses are controlled by accidental happenings	❑	❑	❑	❑
E 6. I can only do what my doctor tells me to do	❑	❑	❑	❑
E 7. There are so many strange diseases around that you can never know how or when you might pick one up	❑	❑	❑	❑
I 8. When I feel ill, I know it is because I have not been getting the proper exercise or eating right	❑	❑	❑	❑
E 9. People who never get sick are just plain lucky	❑	❑	❑	❑
I 10. People's ill health results from their own carelessness	❑	❑	❑	❑
I 11. I am directly responsible for my own health	❑	❑	❑	❑

*I is internally worded, E is externally worded. The scale is scored in the external direction, with each item scored from 1 (strongly disagree) to 4 (strongly agree) for the externally worded items and reverse scored for the internally worded items.

Appendix V. Social Neworks Questionnaire

Rand Social Activities Questionnaire

(Adapted with permission from Donald, C.A., Ware, J.E., Brook, R.H., and Davies-Avery, A. (1978). *Conceptualization and measurement of health for adults in the Health Insurance Study: Vol. IV Social Health,* Rand Publication No. R-1987/4/HEW. Rand Corporation Santa Monica)

1. About how many families in your neighbourhood are you well enough acquainted with, that you visit each other in your homes ? _____ families

2. About how many *close* friends do you have — people you feel at ease with and can talk with about what is on your mind ? (You may include relatives) _____ close friends

3. Over a year's time, about how often do you get together with friends or relatives, like going out together or visiting in each other's homes ?

Every day	.....	1
Several days a week	.....	2
About once a week	.....	3
2 or 3 times a month	.....	4
About once a month	.....	5
5 to 10 times a year	.....	6
Less than 5 times a year	.....	7

4. During the *past month,* about how often have you had friends over to your home ? (Do *not* count relatives)

5. About how often have you visited with friends at *their* homes during the *past month* ? (Do *not* count relatives)

6. About how often were you on the telephone with close friends or relatives during the *past month* ?

7. About how often did you write a letter to a friend or relative during the *past month* ?

8. In general, how well are you getting along with other people these days — would you say better than usual (1), about the same (2) or not as well as usual (3) ?

9. How often have you attended a religious service during the *past month* ?

Response categories items 4,5,6,7,9:

1	Every day
2	Several days a week
3	About once a week
4	2 or 3 times in past month
5	Once in past month
6	Not at all in past month

10. About how many voluntary groups or organisations do you belong to — like church groups, clubs or lodges, parent groups, etc. ('Voluntary' means because you want to)

_____ groups or organisations (Write in number. If none, enter '0')

11. How active are you in the affairs of these groups or clubs you belong to ? (If you belong to a great many just count those you feel closest to. If you don't belong to any, circle 4)

Very active, attend most meetings	.....	1
Fairly active, attend fairly often	.....	2
Not active, belong but hardly ever go	.....	3
Do not belong to any groups or clubs	.....	4

Recoding instructions for individual items

Item	Recoding (original = revised)
Neighbourhood family acquaintances	(0 = 0)(1 = 1)(2 = 2)(3 = 3)(4 = 4) (5 thru 10 = 5)(11 or higher = 6)
Close friends and relatives	(0 = 0)(1 = 1)(2 = 2)(3 = 3)(4 = 4) (5 thru 9 = 5)(10 thru 20 = 6)(21 thru 25 = 7)(26 thru 35 = 8)(36 or higher = 9)
Visits with friends/relatives	(1 thru 3 = 4)(4 = 3)(5,6 = 2)(7 = 1)
Home visits by friends	(1 thru 4 = 3)(5 = 2)(6 = 1)
Visits to homes of friends	(1 thru 3 = 3)(4,5 = 2)(6 = 1)
Telephone contacts	(1 = 5)(2 = 4)(3,4 = 3)(5 = 2)(6 = 1)
Getting along	(1 = 3)(2 = 2)(3 = 1)
Attendance at religious services	(1,2 = 5)(3 = 4)(4 = 3)(5 = 2)(6 = 1)
Voluntary group membership	(0 = 0)(1 = 1)(2 = 2)(3 = 3)(4 = 4) (5 or higher = 5)
Level of group activity	(1 = 4)(2 = 3)(3 = 2)(4 = 1)

because of the heterogeneity of item content and weak inter-item correlations. In order to calculate scores for multi-item measures it is necessary to standarize item scores because of substantially differing variances between items.

Appendix VI. Self-complete questionnaires phase I

Lifestyle and Coronary Surgery Project: Phase I

The enclosed questionnaires are designed to assess your general health and well-being. We would like you to complete them before your visit to the Royal. At the outpatient appointment at the Royal your blood pressure will be checked, height and weight measured and a blood sample taken for cholesterol measurement as well.

Please bring your completed questionnaires.
A similar check-up will be carried out approximately one year following your operation.
Your doctor will be given a report of the results.

Thank you for taking time to complete this information.

1. **Angina**

Angina and breathlessness are symptoms that you are may experience, could you give an estimate of the influence it has on your health.

On a scale of **0 to 7**, where zero represents **no affect to your overall well-being and health** and 7 represents **complete disability, discomfort and restriction to life,** place a point on the scale which most represents the impact that angina and breathlessness has to your quality of life, at this point in time, in terms of

Angina 0●-----●-----●-----●-----●-----●-----●-----●7

Breathlessness 0●-----●-----●-----●-----●-----●-----●-----●7

2. Short-form 36 Questionnaire (Appendix III)

3. Health Locus of Control Questionnaire (Appendix IV)

4. Social Networks Questionnaire (Appendix V)

Appendix VII. Structured Interview Schedule Phase I

Lifestyle and Coronary Surgery Project Phase I

Structured Interview Schedule

Study

Number □□□

1. Patient Details

Date __/__/__ **Date of admission to waiting list** __/__/__

Surname _____

Forenames_____

Address _____ **Postcode** □□□ □□□

Telephone:_____

Employment status _____ **Previous Occupation**

_____

Date of birth __/__/__ **Unit No.**□.□ □ □ □ □ □

Consultant surgeon_____ **Consultant Cardiologist** _____

GP_____ **Address**_____

Tel No_____

2. Physical Measurements

Height(without shoes) □.□□ m **Weight** □□□.□kg **BMI**□□.□

Waist □□□.□ cm(narrowest circumference below the ribs and above the umbilicus)

Hip □□□.□ cm(broadest circumference between the superior border of the iliac crest and the thigh)

Waist:hip ratio_____

3. Blood pressure : To be recorded using the right arm and after the patient has rested for 5 minutes and 5 minutes between readings.

	1st reading	2nd reading	(nearest 2mm Hg)
Systolic	☐☐☐	☐☐☐	
Diastolic	☐☐☐	☐☐☐	

4. Blood sample

Fasting since? ☐☐.☐☐hrs Blood sample (10ml) ☐

Lipids TC_____ Tg_____ VLDL _____ LDL _____

HDL_____

5. Smoking History

Smoker ☐ 1=yes, 2=Ex, 3=never,

If current smoker ☐☐ cigarettes/day, Years smoking ☐☐

Ex-smoker ☐☐ cigarettes/day Years smoking ☐☐ Time since stopped ☐☐ yrs

6. Alcohol intake per week _____ units

7. Exercise Activity

_____

8. Medical history

a. Diabetes Mellitus ☐ 1=yes, 2=no Age at onset ☐☐yrs No. of years diabetic ☐☐ yrs

Treatment ☐ 1=Diet only, 2=drug, 3= insulin 4=drug+insulin,
5=other _____

b. Do you suffer from any other **Major Medical Problem**

_____

c. Medications

_____

Anti-anginal ☐ 1=yes, 2=no Anti-platelet ☐ 1=yes, 2=no

HRT ☐ 1=yes, 2=no Other ☐ 1=yes, 2=no

9. Personal History of Coronary Heart disease

a. Angina ☐ 1=yes, 2=no Age at onset ☐☐ yrs

Heart Attack ☐ 1=yes, 2=no	Age at 1st MI ☐☐ yrs	No. of MI ☐
Previous coronary surgery ☐	1=yes, 2=no	Age ☐☐ yrs
Previous coronary angioplasty ☐	1=yes, 2=no	Age ☐☐ yrs

Angiography findings (No. of vessels diseased)_____

Section 2

Structured Interview Phase I

1. The questionnaire (SF-36) has been designed to measure levels of general health. Did you have any difficulties completing the form? How applicable do you think the questions are to your health?

2. How would you describe your general health and well-being?

3. How do you expect the CABG surgery to affect your general health and well-being?

Appendix VIII. Subject Invitation Letter

Direct Tel. No. 0141-211-4332

September 1995

Dear

I am a Nursing Sister working as part of the Cardiac Surgery group at the Royal Infirmary. We are assessing health and well-being of patients awaiting coronary surgery and again one year following surgery. Your help with this assessment will help us to provide better care for patients in the future.

We are therefore writing to ask if you would be willing to participate in this work. Briefly, it involves a visit to the Royal Infirmary before the time of your operation to have your blood pressure checked, height and weight measured, a blood sample for cholesterol measurement and a questionnaire to complete on your general health. A similar check-up will be carried out approximately one year following your operation. Your doctor will be given a report of the results.

If you are interested in taking part, or perhaps would like to have more information about this work first, please complete the tear off slip at the bottom of the page and return with the pre-paid addressed envelope enclosed.

Thank you for taking time to consider this request.

Yours sincerely

Grace M Lindsay
Research Sister

I am interested in taking part in the study Yes ❑ No ❑

If you are interested a morning appointment time will be sent to you, please indicated times that are not suitable,

_____

I would like more information, please contact me at :

Tel:_____

Appendix IX. Self-complete questionnaires phase II

Coronary artery bypass surgery project Phase II

I hope you are feeling well and have made a good recovery from your operation. Thank you for the valuable help you provided when you completed the large number of questions prior to your operation. To help us find out more about the benefits of surgery I am again asking for your help to complete the attached questionnaires at this time of approximately a year since your surgery. I also would like you to attend the clinic again for the same check up you had when you came to see me before your operation i.e. blood pressure, weight and a blood sample to check your cholesterol level.

Please bring these completed questionnaires with you when you come along to your clinic appointment:

Date **Time**

If possible please come fasted i.e. have nothing to eat or drink other than water from 10pm the evening before.

Many thanks

Grace Lindsay
Lecturer

Tel: 0141-330 6876
0141-211 4000 (Radiopage)

---

1. In general would you rate your health and wellbeing since the operation as

Much ☐ better ☐ same ☐ worse ☐ much ☐
better worse

2. Since your operation have you had any angina symptoms? ☐ **Yes/No**

If your answer is **yes**, on a scale of 0 to 7, where zero represents **no affect on your overall well-being and health** and 7 represents **complete disability, discomfort and restriction to life,** place a point on the scales which most represents the impact that angina has to your quality of life at this point in time in terms of

Angina pain 0●-----●-----●-----●-----●-----●-----●-----●7

Breathlessness 0●-----●-----●-----●-----●-----●-----●-----●7

3. Recall

Could you recall the level of discomfort that your anginal symptoms were like just **before surgery,** on the same scales?

Angina pain 0●-----●-----●-----●-----●-----●-----●-----●7

Breathlessness 0●-----●-----●-----●-----●-----●-----●-----●7

4. What medication or tablets are you currently taking ?

_____

_____

_____

5. Did you attend a cardiac rehabilitation programme ? ❑ **Yes/No**

If **No,** give reasons

_____

_____

If **yes** for what length of time ?

_____

Were there particular parts of the course that you liked?

_____

_____

_____

Were there particular parts of the course that you disliked?

_____

_____

_____

6. Have you been admitted to hospital since your operation? ❑ **Yes/No**

If **yes** , please give reason and length of time for each episode_____

_____

_____

7. Short-form 36 Questionnaire (Appendix III)

8. Health Locus of Control Questionnaire (Appendix IV)

9. Social Networks Questionnaire (Appendix V)

Appendix X. Structured interview schedule phase II

Lifestyle and Coronary Surgery Project

Structured Interview Schedule Phase II

Study Number □□□

1. Patient Details

Date __/__/__ **Date of operation** __/__/__ **Time since op** □□ mths

Name._____

2. Operative details

admission date __/__/__ discharge date __/__/__ length of stay □□days

No. of vessels bypassed □ Use of IMA □ leg □ 1= one leg, 2=both legs, 3=not used

3. Physical measurements

Height(without shoes) □□□.□cm **Weight** □□□.□kg **BMI** □□.□

Waist □□□.□ cm(narrowest circumference below the ribs and above the umbilicus)

Hip □□□.□ cm(broadest circumference between the superior border of the iliac crest and the thigh)

Waist:hip ratio_____

4. Blood pressure : To be recorded using the right arm and after the patient has rested for 5 minutes and 5 minutes between readings. (nearest 2mm Hg)

	1st reading	2nd reading
Systolic	□□□	□□□
Diastolic	□□□	□□□

5. Blood sample for lipid measurement

Fasting since? ☐☐.☐☐hrs Blood sample(10ml) ☐ Lipids

6. Smoking History

Smoker ☐ 1=yes, 2=Ex,, 3=never

If current smoker ☐☐ cigarettes/day

did you stop prior to surgery? ☐1=yes, 2=no

Ex-smoker ☐☐ cigarettes/day Years smoking ☐☐ yrs

Time since stopped ☐☐ yrs

7. Alcohol intake ☐☐ units per week

8. Medical history

a. Diabetes Mellitus ☐ 1=yes, 2=no

When was diagnosis made __/__/__

Treatment☐ 1=Diet only, 2=drug, 3= insulin 4=drug+insulin,

5=other_____

_____

b. Any other health problems

_____

_____

Section 2

Structured Interview Phase II

1. Can you tell me about your experience of having coronary artery bypass surgery?

2. How do you believe the CABG surgery has affected your health?

Appendix XI. Validation of thematic analysis

15 September 1998

Sister Elizabeth Keith
Cardiac Rehabilitation Department
Glasgow Royal Infirmary
Castle Street
Glasgow
G4 0SF

Dear Liz

Health Status and Outcome Following CABG Surgery

As part of a prospective study of health outcome that I am undertaking for study towards a PhD, I have been interviewing patients with regard to their views on aspects of life important to them, both pre-surgery (approximately 1 month) and post surgery (approximately 15 months).

These abbreviated comments represent their concerns and issues raised and will be used to complement the health status measurement tool short-form-36 to hopefully provide a truer account of the lived experience. It is recommended in the employment of this methodology that clinicians with knowledge and expertise of working with individuals with coronary heart disease in general and with patients who have undergone coronary artery bypass surgery who would be willing to review these comments to provide an independent view of how typical or expected you find the thematic analysis of the interviews. Please be guided by your own experience :

- Are the comments expected/unexpected/typical?
- Do they make sense?
- Do they 'ring true'?
- Are there any interesting surprises?

Many thanks for your time and effort.

Yours sincerely

GRACE LINDSAY

Exemplar from thematic analysis of structured interview responses

Phase I question: How do you expect the CABG surgery to affect your general health and well-being?

Phase II question: How do you believe the CABG surgery has affected your health?

Hosp No.	Phase I	Theme
79712	hopes op will be of benefit but not sure	hope, chance and uncertainty
190806	improve quality of life	life to years
549114	be a new man, rid of pain	life to years
707018	expect to live till 70-80	years to life
672232	frightened to go too far a distance walking, cant get back	freedom and independence
640982	guaranteed 20 -30 years as long as stops smoking	years to life
666545	will be a new man after the op	life to years
722329	hope to be a lot fitter but wont get back to full fitness	hope, chance and uncertainty
95323	limited in activities particularly walking hills and stairs	freedom and independence
673913	to be able to do things presently restricted, functional gain	freedom and independence
Hosp No.	**Phase II**	**Theme**
578477	feel that something could happen at any time,	Removal of a death sentence
682988	I feel less at risk of heart attack	Removal of a death sentence
893299	it knocked hell out of me	Enormity of the experience
626060	I thought it was a shattering experience	Enormity of the experience
247204	if hadnt had op wouldnt be here to-day	Removal of a death sentence
688908	it was like being in the trenches, we looked out for each other	Lay support
900966	I made friends in hospital and that helped so much	Lay support
925822	great success, could go out and do what he wanted	Freedom of choice
653333	I can do almost anything I want to	Freedom of choice
611388	not sitting waiting and worrying that something might happen to he	Removal of a death sentence

Comments on thematic analysis from Cardiac Nurse Specialist

GLASGOW ROYAL INFIRMARY
AUSPICE CÆLO
University N.H.S. Trust

• Glasgow Royal Infirmary •
• Glasgow Royal Maternity Hospital •
• Canniesburn Hospital •
• Lightburn Hospital •

Royal Infirmary
84 Castle Street
Glasgow G4 0SF

Switchboard: 0141 211 4000
Direct Dial: 0141 211 4009
Fax Number:

Cardiac Rehabilitation,
3rd Floor, Walton Building

22/9/98

Grace Lindsay
Lecturer in Nursing Studies
Glasgow University.

Dear Grace,
Thank you for allowing me the honour of reading your document. The comments attributed to the patients concerning their experiences both prior to CABG and post-operatively are very typical in my experience.

It is interesting that you identify the problems which arise with questionnaires used with this group of patients. They do indeed have problems answering a straight 'yes' or 'no' because of the variability of their symptoms depending on the weather, hills, 'good days and bad days' etc.

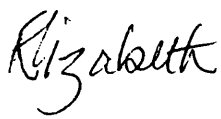
The comment by one patient 'did the surgeons know what a crushing blow it was to be told that I needed surgery?' is a reminder to those of us working in the health care profession that the hospital is an alien world for the majority of patients whilst it is our second home! The hospital layout, the staff and procedures are very familiar to us and it would be easy to forget the impact of this environment on the patient and relative.

The fear of impending crisis seems to loom large over many patients awaiting CABG. The placement of a nurse to support these patients pre-surgery, which is now in place, will be of enormous benefit in maximising their fitness for surgery and reducing their anxiety.

I was interested that a large number of patients were unclear as to the effect of CABG would have on their health. We at rehabilitation only see a fraction of patients awaiting surgery and I was not aware of that issue. I have always understood that the surgeons spell out the percentage of risk and the expected success rate of the operation but perhaps this is another indication of the inability of the anxious patient to absorb and retain information. Some of our post CABG patients have been told they will 'feel like a new man/woman' which I think is a bit misleading as they very soon discover the rest of their body remains the same age post-operatively as it was pre-operatively! The perception that CABG was a 'cure' may indicate why many patients feel post-operatively that the health education talks are not necessary. We try to point out gently that CHD is a progressive disease and requires vigilance.

Thank you again for sharing your findings with me.

Yours sincerely



Elizabeth Keith
Cardiac Rehabilitation Sister.

Appendix XII. Summary of variables measured in study subjects

variable name	variable meaning
Age	Age of subject at time of CABG surgery.
age-at-onset	Age at onset of CHD.
Alcohol I/II	Weekly alcohol consumption of alcohol in units at phase I/II.
Angina I/II	Angina self-rated score at phase I/II of study.
Angina I/II (y=1/n=0)	A categorical variable with value one if subject has anginal symptoms at phase I/II and zero otherwise.
Angina I/II (+ve)	Angina self-rated score for those who have angina at phase I/II. Undefined for patients without anginal symptoms.
Breath I/II	Breathlessness self-rated score at phase I/II of study.
Breath I/II (y=1/n=0)	A categorical variable with value one if a subject has breathlessness symptoms at phase I/II and zero otherwise.
Breath I/II (+ve)	Breathlessness self-rated score for those who have angina at phase I/II. Undefined for patients without breathlessness symptoms.
BMI I/II	Body mass index at phase I/II.
cholesterol I/II	Plasma cholesterol level at phase I/II.
current smoker I/II	A categorical variable with value one if a subject currently smokes and zero otherwise.
past smoker I/II	A categorical variable with value one if a subject smokes now or has smoked in the past and zero otherwise.
depcat	Castairs deprivation category.
diabetes mellitus	Categorical variable with value one for subjects suffering from diabetes mellitus and zero otherwise.
DBP I/II	Diastolic blood pressure at phase I/II.
SBP I/II	Systolic blood pressure at phase I/II.
gender	female=0 and male=1
HLOC I/II	Health locus of control at phase I/II.
MI	Categorical variable with value one if subject has had a myocardial infarction and zero otherwise.
NYHA	Angina grading score.
risk I/II	Number of CHD risk factors above target levels at phase I/II.
SOC I/II	Social networks score at phase I/II.
waist I/II	Waist circumference (cm) at phase I/II.
wait	Waiting time (days) for CABG surgery.
weight I/II	Weight (kg) at phase I/II.

SF-36 health domains

Variable name	Variable meaning
SF-36 I/II BP	Phase I/II SF-36 measurement of bodily pain.
SF-36 I/II EV	Phase I/II SF-36 measurement of energy and vitality.
SF-36 I/II GH	Phase I/II SF-36 measurement of general health.
SF-36 I/II MH	Phase I/II SF-36 measurement of mental health.
SF-36 I/II PF	Phase I/II SF-36 measurement of physical function.
SF-36 I/II RE	Phase I/II SF-36 measurement of emotional role limitation.
SF-36 I/II RP	Phase I/II SF-36 measurement of physical role limitation.
SF-36 I/II SF	Phase I/II SF-36 measurement of social function.

Appendix. XIII. Bivariate correlation* (Pearson) of SF-36-I domains with phase I variables

SF-36-I	BP	EV	GH	MH	PF	RE	RP	SF
Age (yrs)	0.127	0.036	0.022	**0.204**	0.028	0.084	-0.043	0.033
	(203)	(201)	(202)	(201)	(202)	(200)	(201)	(202)
Age at	**0.166**	0.060	0.131	0.099	0.089	0.124	-0.058	-0.017
Onset (yrs)	(184)	(182)	(183)	(182)	(183)	(181)	(182)	(183)
alcohol	-0.023	-0.039	0.022	-0.055	0.140	0.017	0.042	0.131
(units/week)	(182)	(180)	(181)	(181)	(181)	(179)	(18)	(181
angina I	-0.059	-0.031	-0.031	-0.002	-0.018	0.007	-0.050	-0.066
(yes/no)	(203)	(202)	(203)	(202)	(203)	(201)	(202)	(203)
angina I	**-0.148**	-0.077	**-0.183**	-0.047	**-0.142**	-0.003	-0.061	-0.029
(+ve)	(191)	(190)	(191)	(190)	(191)	(190)	(190)	(191)
BMI I	0.000	-0.028	-0.069	-0.010	-0.020	0.029	**-0.157**	-0.084
	(205)	(203)	(204)	(203)	(204)	(202)	(203)	(204)
breath I	-0.103	-0.129	-0.104	-0.051	-0.103	-0.056	-0.059	-0.099
(yes/no)	(203)	(202)	(203)	(202)	(203)	(201)	(202)	(203)
breath I	-0.112	-0.055	-0.105	-0.040	-0.040	-0.051	**-0.162**	-0.034
(+ve)	(188)	(187)	(188)	(187)	(188)	(186)	(187)	(188)
Tchol I	-0.037	-0.024	-0.052	-0.033	-0.082	-0.006	-0.094	-0.100
(mmol/l)	(184)	(182)	(183)	(182)	(183)	(181)	(182)	(183)
current	-0.088	-0.117	**-0.185**	**-0.141**	-0.106	-0.121	-0.109	-0.065
smoker I	(205)	(203)	(204)	(203)	(204)	(202)	(203)	(204)
past	-0.022	-0.071	-0.096	-0.129	-0.007	-0.134	-0.024	0.015
smoker I	(205)	(203)	(204)	(203)	(204)	(202)	(203)	(204)
diabetes	-0.111	-0.019	-0.117	-0.056	-0.127	-0.028	-0.081	-0.050
mellitus	(205)	(203)	(204)	(204)	(204)	(202)	(203)	(204)
depcat	**-0.207**	**-0.161**	-0.117	**-0.152**	**-0.162**	-0.032	-0.126	**-0.202**
	(205)	(203)	(204)	(203)	(204)	(202)	(203)	(204)
HLOC I	-0.051	-0.105	**-0.198**	-0.133	-0.086	0.005	-0.012	0.004
	(173)	(173)	(173)	(173)	(173)	(171)	(172)	(173)
No. vessels	-0.132	-0.130	**-0.148**	0.002	-0.063	-0.017	**-0.151**	-0.133
diseased	(202)	(200)	(201)	(200)	(201)	(199)	(200)	(201)
risk I	-0.019	-0.035	**-0.151**	-0.047	-0.054	-0.011	-0.130	-0.142
	(183)	(181)	(182)	(181)	(182)	(180)	(181)	(182)
SOC I	**0.147**	**0.196**	**0.149**	**0.194**	**0.201**	**0.187**	0.140	**0.179**
	(179)	(179)	(179)	(179)	(179)	(177)	(178)	(179)
SBP I	-0.004	0.136	0.109	0.049	0.005	0.031	0.002	0.008
(mm Hg)	(202)	(200)	(201)	(200)	(201)	(199)	(200)	(201)
wait (days)	0.019	-0.030	-0.117	-0.089	**-0.192**	0.083	-0.049	0.084
	(201)	(199)	(200)	(199)	(200)	(198)	(199)	(200)

Appendix XIV. Summary statistics for SF-36 scores at phase II assessment

Summary statistics of SF-36-II domain scores

SF-36-H	PF	RP	BP	GH	EV	SF	RE	MH
Sample size	180	176	178	180	179	179	170	179
Mean	57.0	40.9	61.1	54.7	48.3	68.9	51.6	66.1
25th percentile	30.8	0.0	44.4	37.0	30.0	44.4	0.0	52.0
50th percentile	60.0	0.0	61.1	57.0	50.0	77.8	25.0	68.0
75th percentile	84.6	0.0	88.9	72.0	65.0	100	100	80.0
std. Deviation	29.2	45.4	25.9	24.0	23.4	29.6	46.3	18.4
% ceiling	5.0	8.4	19.1	1.7	1.1	28.5	44.1	1.1
% floor	0.6	76.8	1.7	1.1	1.7	2.2	39.4	1.7

Appendix XV. Correlations between all eight domains of the SF-36 scales at baseline and follow-up assessment.

SF-36 domain	SF-36-II BP	SF-36-II EV	SF-36-II GH	SF-36-II MH	SF-36-II PF	SF-36-II RE	SF-36-II RP	SF-36-II SF
SF-36-I BP	**0.330** (170)	**0.296** (171)	**0.218** (172)	**0.241** (171)	**0.301** (172)	**0.198** (164)	**0.287** (169)	**0.302** (171)
SF-36-I EV	**0.219** (168)	**0.462** (169)	**0.277** (170)	**0.261** (169)	**0.309** (170)	**0.261** (162)	**0.292** (167)	**0.267** (169)
SF-36-I GH	**0.152** (169)	**0.266** (170)	**0.257** (171)	**0.162** (170)	**0.229** (171)	**0.248** (163)	**0.175** (168)	**0.192** (170)
SF-36-I MH	**0.251** (168)	**0.336** (169)	**0.222** (170)	**0.355** (169)	**0.353** (170)	**0.379** (162)	**0.245** (167)	**0.273** (169)
SF-36-I PF	**0.211** (169)	**0.262** (170)	**0.234** (171)	**0.207** (170)	**0.341** (171)	**0.209** (163)	**0.239** (168)	**0.306** (170)
SF-36-I RE	**0.195** (168)	**0.250** (169)	**0.153** (170)	**0.269** (169)	**0.242** (170)	**0.315** (162)	**0.263** (167)	**0.291** (169)
SF-36-I RP	**0.155** (168)	**0.277** (169)	**0.169** (170)	**0.247** (169)	**0.201** (170)	**0.226** (162)	**0.319** (167)	**0.203** (169)
SF-36-I SF	**0.173** (169)	**0.318** (170)	**0.228** (171)	**0.265** (170)	**0.330** (171)	**0.266** (163)	**0.292** (168)	**0.350** (170)

* Significant correlations are indicated in bold

The correlation coefficient between any pair of SF-36 baseline and follow-up scores is sufficiently large to be statistically significant. However, strengths of correlation are necessarily tempered by the fact that each domain measures a distinctive element of general health, not necessarily present to the same degree in other measures, and by a high level of contaminating noise.

Although it might appear better to correlate differences in SF-36 scores between baseline and follow-up with, for example baseline scores, the artificially high correlations generated in this way are meaningless since they are simply artifacts of the high and often perfect correlations that exist between the baseline SF-36 scores themselves.

Appendix XVI. Regression graphs for SF-36 II scores versus phase I variables

Introduction

This appendix contains the histograms of residuals, graphs of residuals versus predicted variables and the normal scores plot for the regression of each SF-36-II score versus phase I variables.

SF-36 Bodily Pain

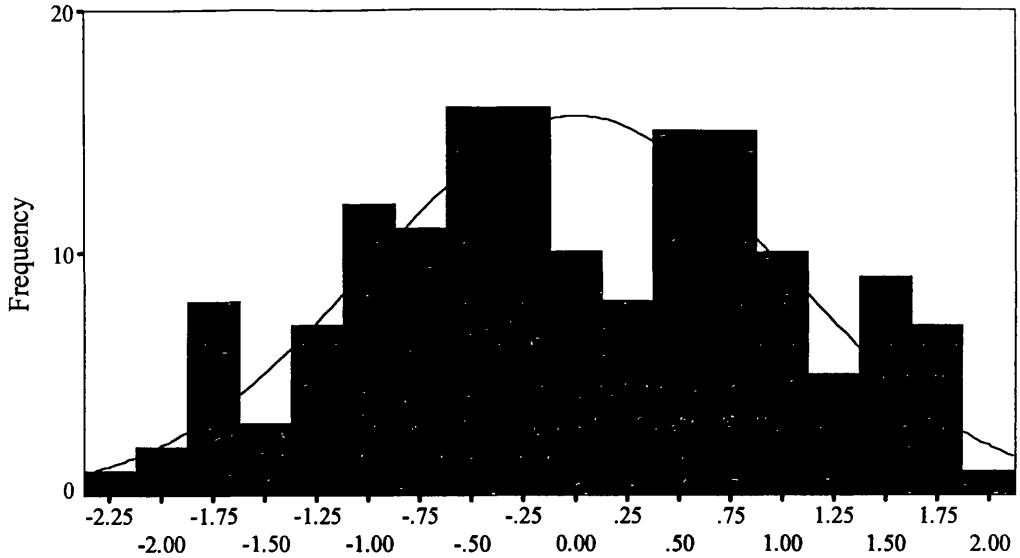
SF-36-II BP was regressed against the phase I variables SF-36-I BP (X_1), and social network score (X_2) to give

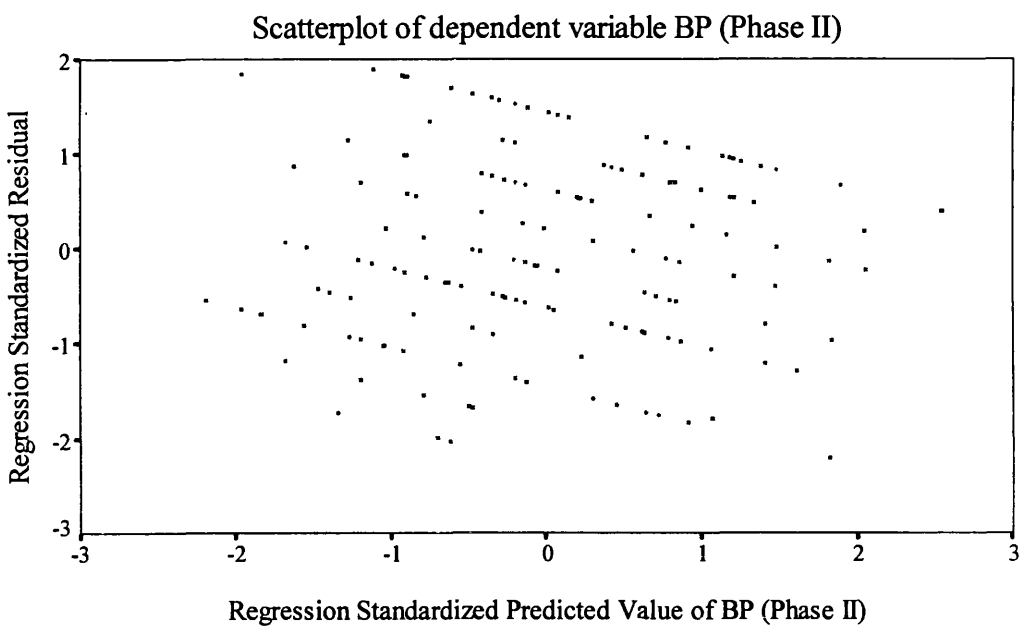
$$BP = 26.74 + 0.35X_1 + 0.80X_2$$

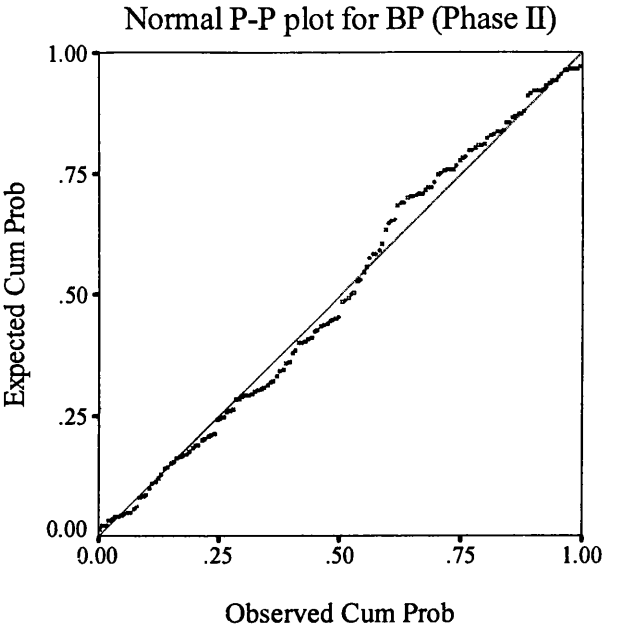
The regression analysis is based on 155 subjects and has an adjusted R^2 value of 13.6%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2
p-value	0.001	<0.001	0.013

The histogram of residuals and their scatter plot versus the standardised predicted values are


20
10
0
Frequency
-2.25
-1.75
-1.25
-.75
-.25
.25
.75
1.25
1.75
-2.00
-1.50
-1.00
-.50
0.00
.50
1.00
1.50
2.00
Regression Standardized Residual for BP (Phase II)


Scatterplot of dependent variable BP (Phase II)
Regression Standardized Residual
2
1
0
-1
-2
-3
-3
-2
-1
0
1
2
3
Regression Standardized Predicted Value of BP (Phase II)



Normal Scores plot for regression

In future, the normal scores plot will be omitted as all future plots are at least as good as this one. The histogram with superimposed normal distribution will suffice to demonstrate the normal character of the residuals.

SF-36 Energy and Vitality

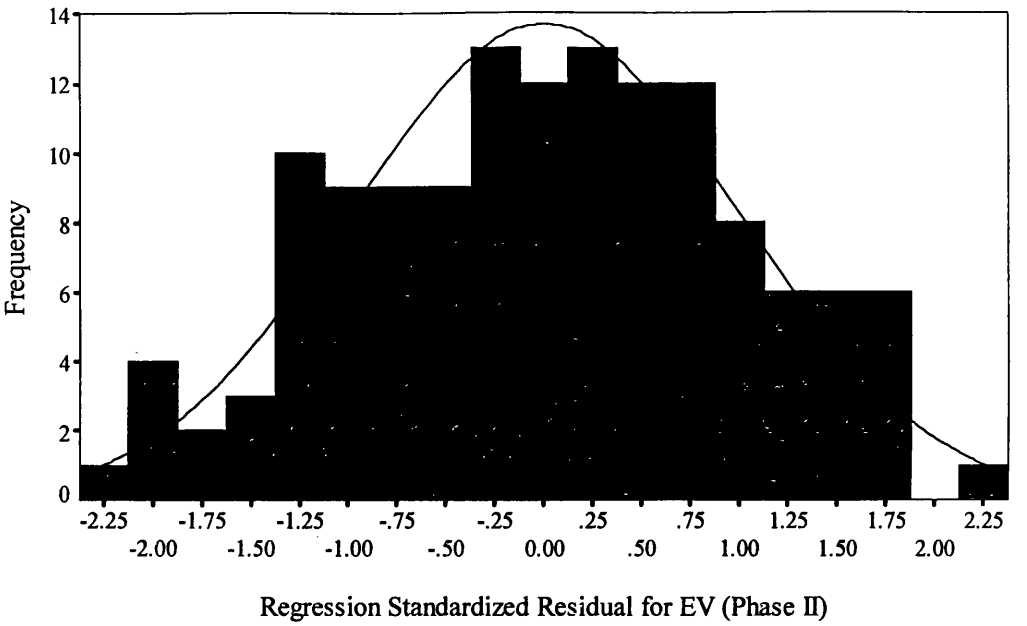
SF-36-II EV was regressed against the phase I variables SF-36-I EV (X_1), social network score (X_2) and alcohol consumption (X_3) to obtain

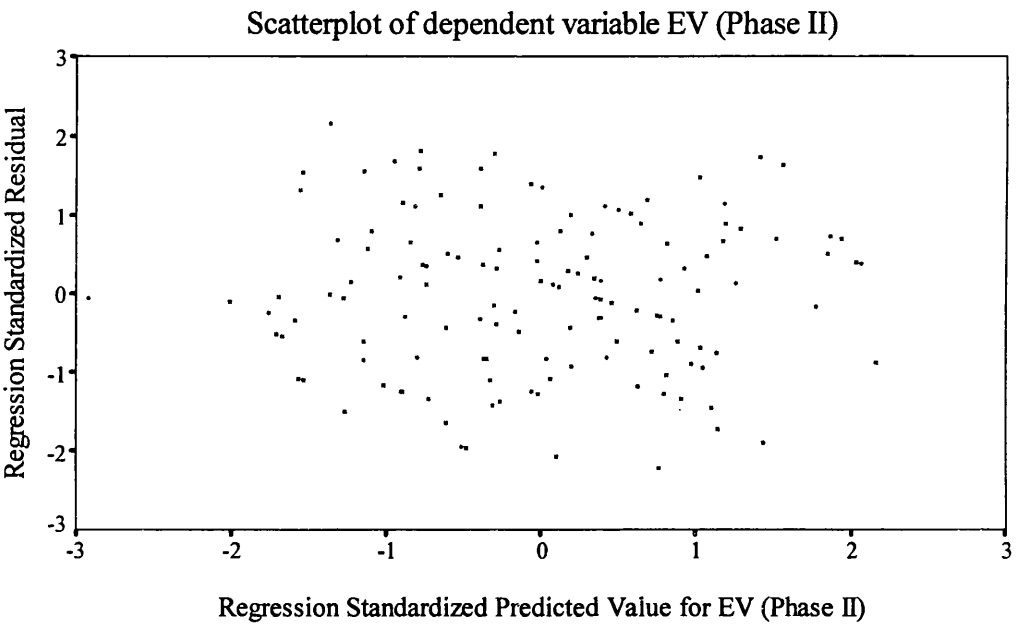
$$EV = 16.52 + 0.48X_1 + 0.63X_2 - 0.32X_3.$$

The regression analysis is based on 135 subjects and has an adjusted R^2 value of 24.6%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	Constant	X_1	X_2	X_3
p-value	0.019	<0.001	0.020	0.032

The histogram of residuals and their scatter plot versus standardised predicted values are presented in the following two figures.





SF-36 General Health

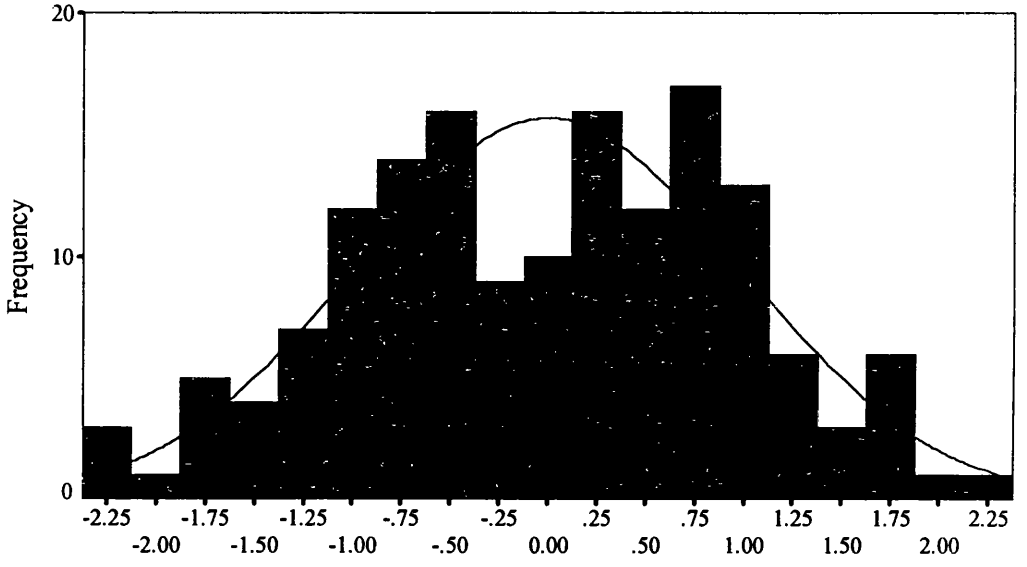
SF-36-II GH was regressed against the phase I variables SF-36-I EV (X_1), social network score (X_2), presence of diabetes mellitus (X_3) and age (X_4) to obtain

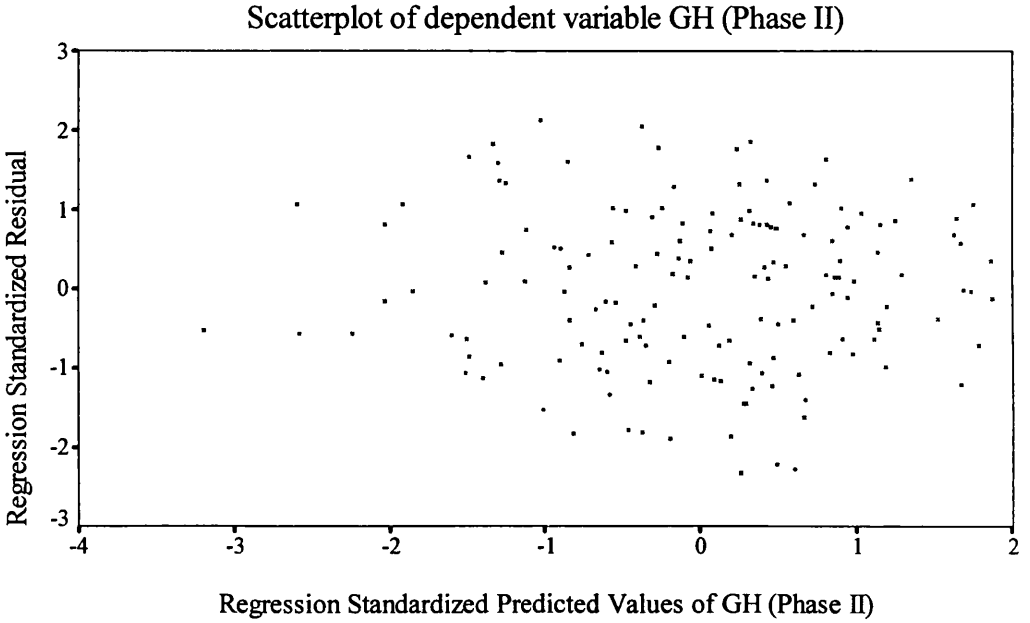
$$GH = 0.99 + 0.28X_1 + 0.61X_2 - 16.33X_3 + 0.53X_4 .$$

The regression analysis is based on 155 subjects and has an adjusted R^2 value of 15.7%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	Constant	X_1	X_2	X_3	X_4
p-value	0.947	<0.001	0.029	0.004	0.029

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Mental Health

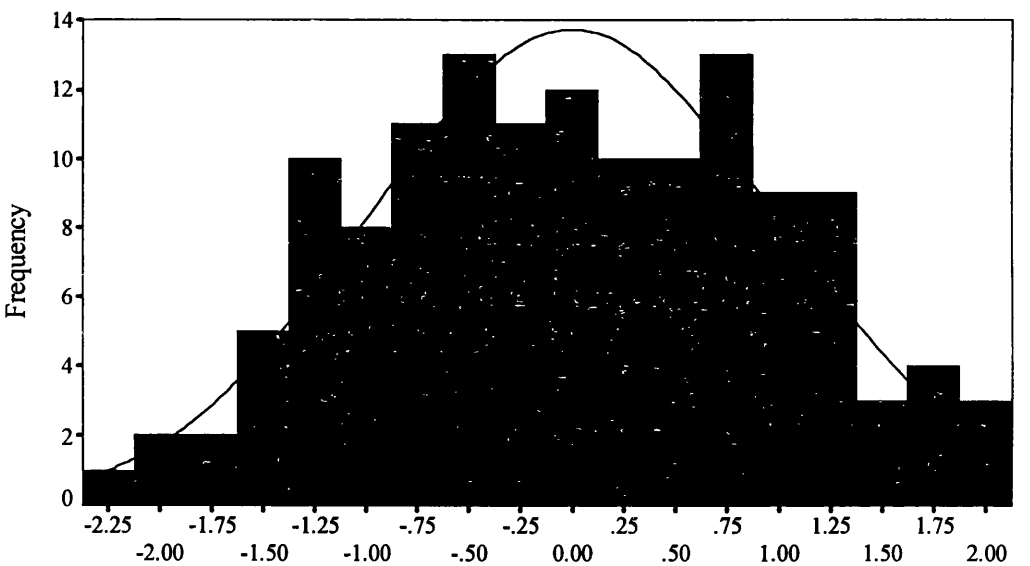
SF-36-II MH was regressed against the phase I variables SF-36-I MH (X_1), social network score (X_2), current smoking status (X_3) and alcohol consumption (X_4) to obtain

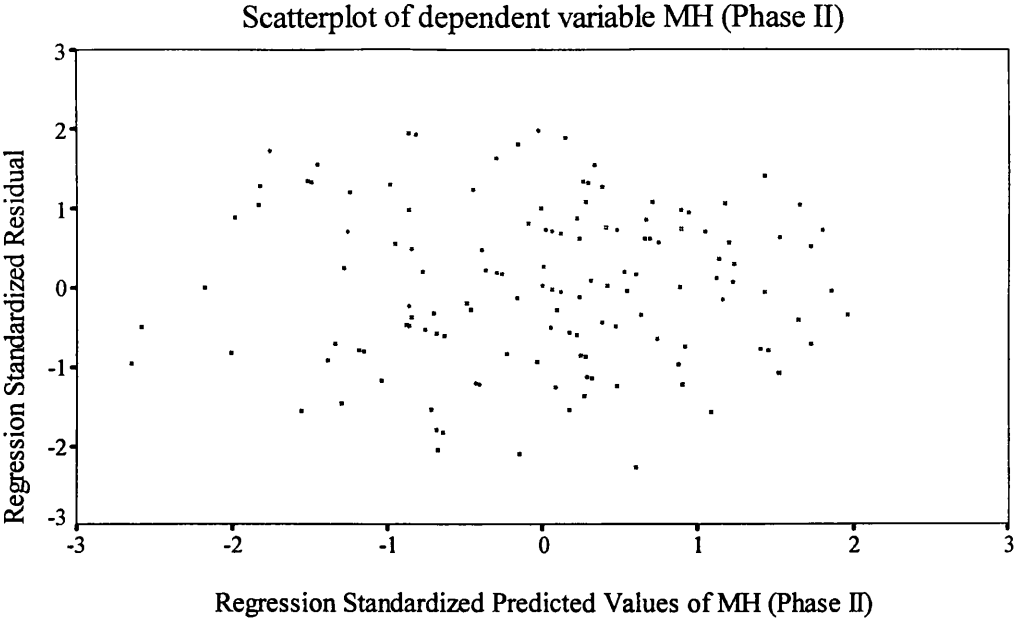
$$MH = 33.38 + 0.27X_1 + 0.75X_2 - 7.63X_3 - 0.28X_4 .$$

The regression analysis is based on 135 subjects and has an adjusted R^2 value of 21.9%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2	X_3	X_4
p-value	<0.001	0.002	<0.001	0.023	0.021

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Physical Function

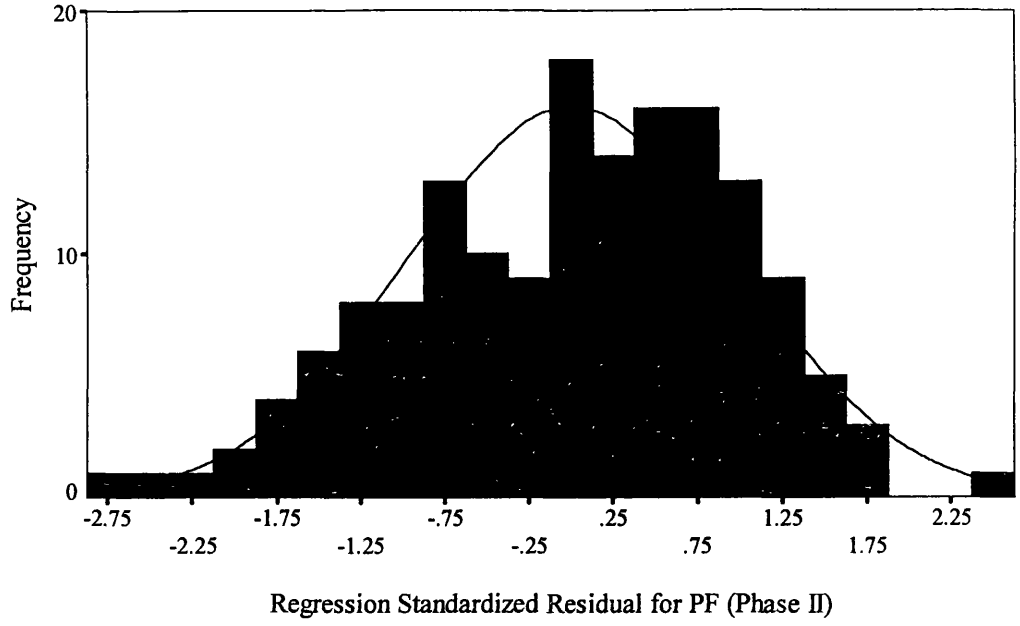
SF-36-II PF was regressed against the phase I variables SF-36-I PF (X_1), SF-36-I MH (X_2), social network score (X_3), presence of diabetes mellitus (X_4), waist circumference (X_5) and weight (X_6) to obtain

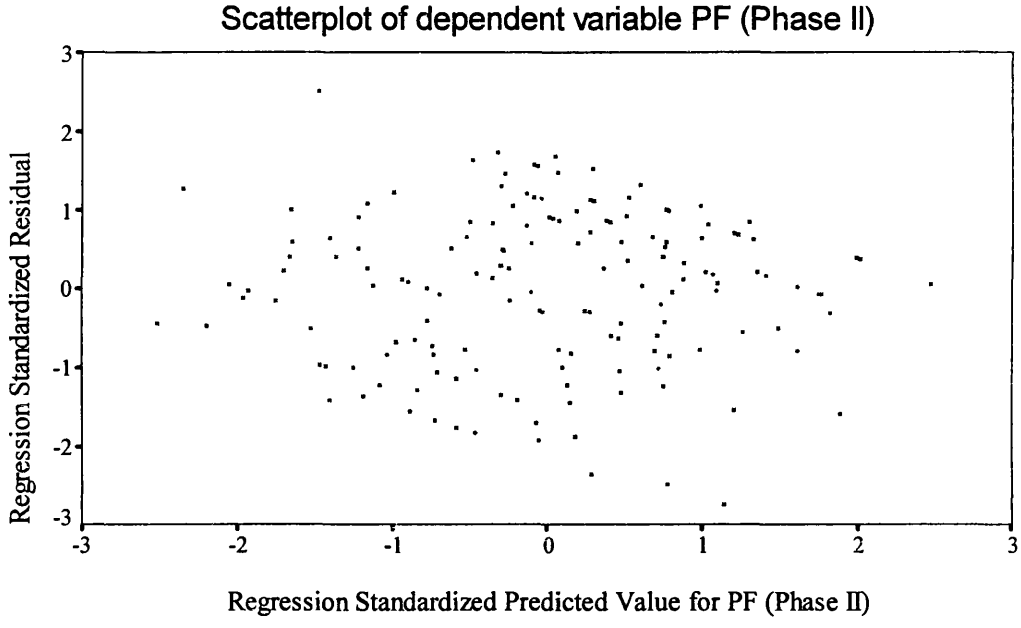
$$PF = 73.26 + 0.19X_1 + 0.34X_2 + 1.16X_3 - 17.31X_4 - 1.27X_5 + 0.68X_6.$$

The regression analysis is based on 157 subjects and has an adjusted R^2 value of 29.5%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2	X_3	X_4	X_5	X_6
p-value	0.005	0.034	0.003	<0.001	0.004	0.002	0.032

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Emotional role limitation

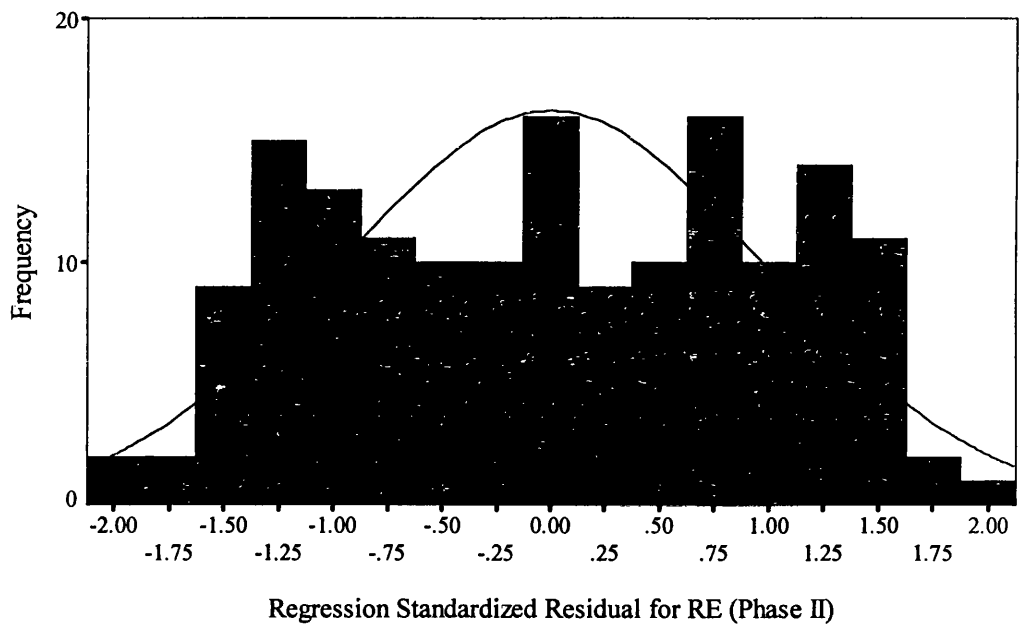
SF-36-II RE was regressed against the phase I variables SF-36-I RP (X_1), SF-36-I MH (X_2), presence of diabetes mellitus (X_3) and past smoking status (X_4) to obtain

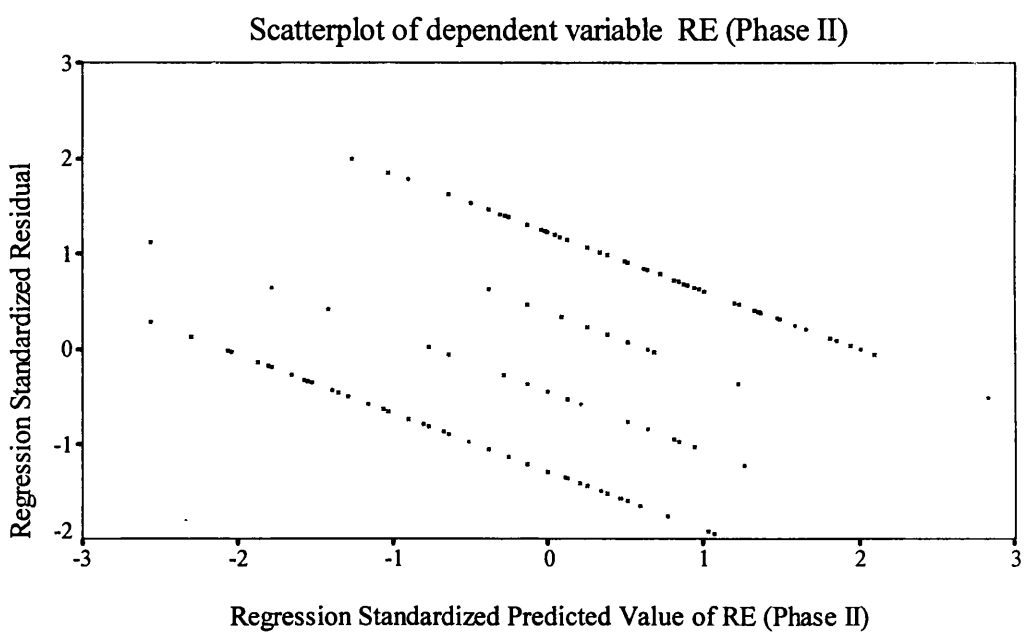
$$RE = 21.56 + 0.23X_1 + 0.79X_2 - 37.22X_3 - 20.71X_4.$$

The regression analysis is based on 160 subjects and has an adjusted R^2 value of 25.9%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2	X_3	X_4
p-value	0.126	0.023	<0.001	<0.001	0.016

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Physical role limitation

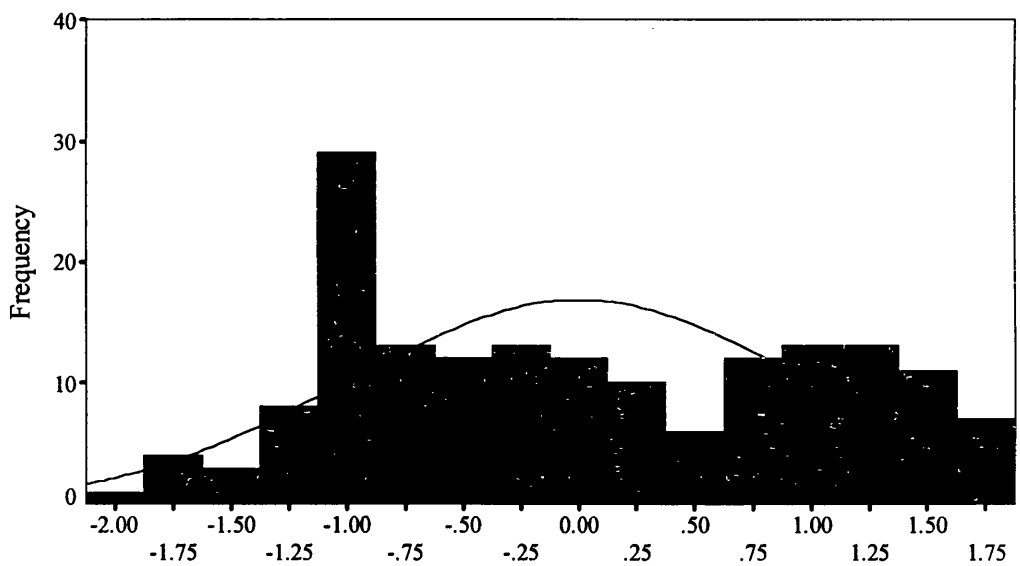
SF-36-II RP was regressed against the phase I variables SF-36-I RP (X_1), social function (X_2), presence of diabetes (X_3) and current smoking status (X_4) to obtain

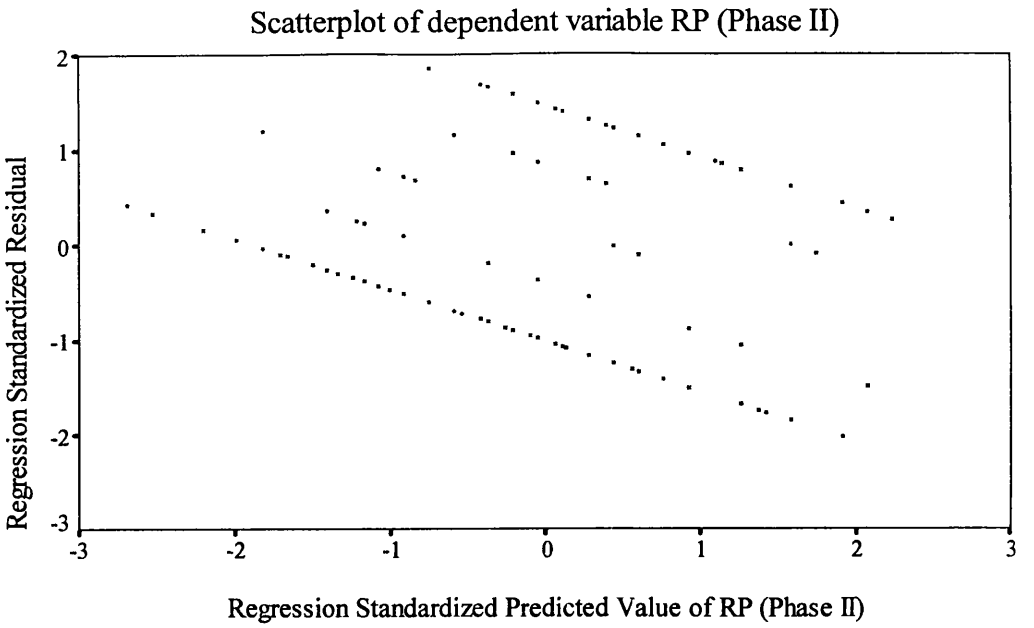
$$RP = 29.14 + 0.28X_1 + 0.32X_2 - 34.81X_3 - 18.72X_4 .$$

The regression analysis is based on 160 subjects and has an adjusted R^2 value of 25.9%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2	X_3	X_4
p-value	<0.001	0.010	0.011	<0.001	0.013

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Social function

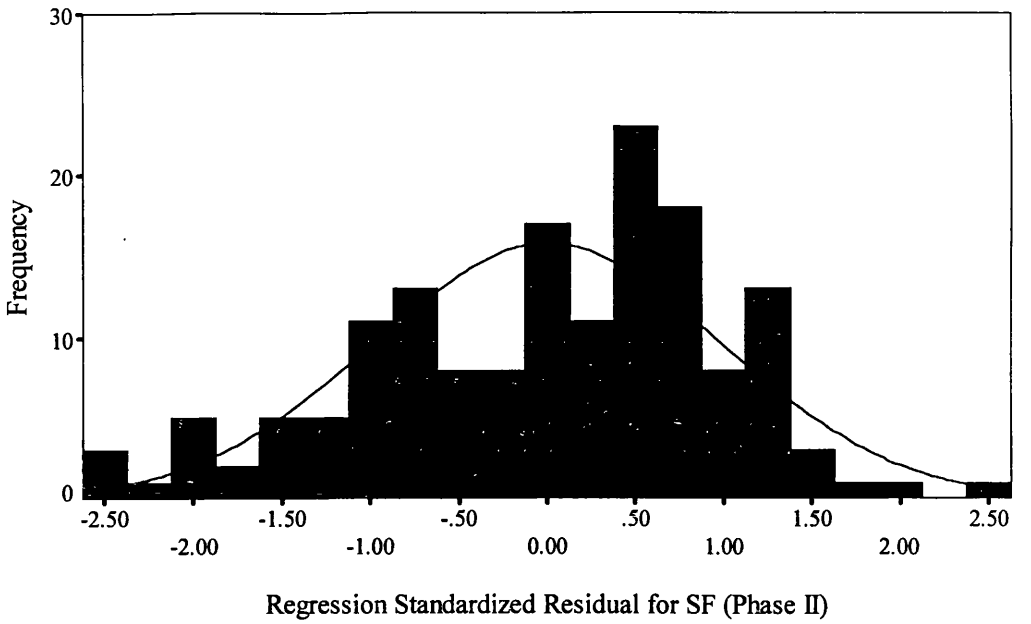
SF-36-II SF was regressed against the phase I variables SF-36-I SF (X_1), social network score (X_2) and current smoking status (X_3) to obtain

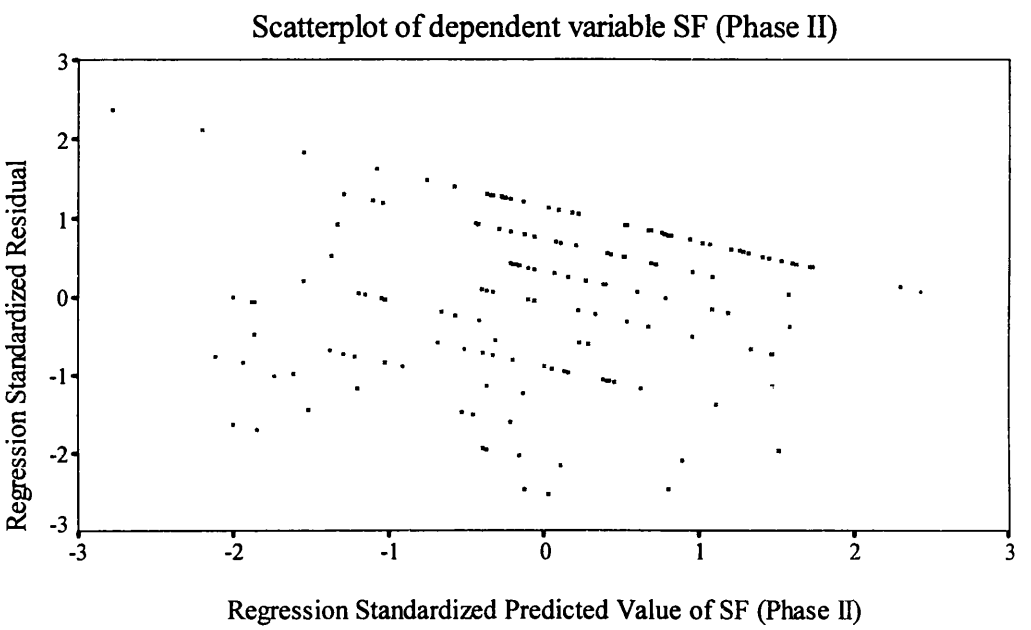
$$SF = 38.44 + 0.29X_1 + 0.77X_2 - 11.68X_3 .$$

The regression analysis is based on 156 subjects and has an adjusted R^2 value of 15.1%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

variables	constant	X_1	X_2	X_3
p-value	<0.001	<0.001	0.020	<0.029

The histogram of residuals and their scatter plot versus standardised predicted values are





SF-36 Mean score

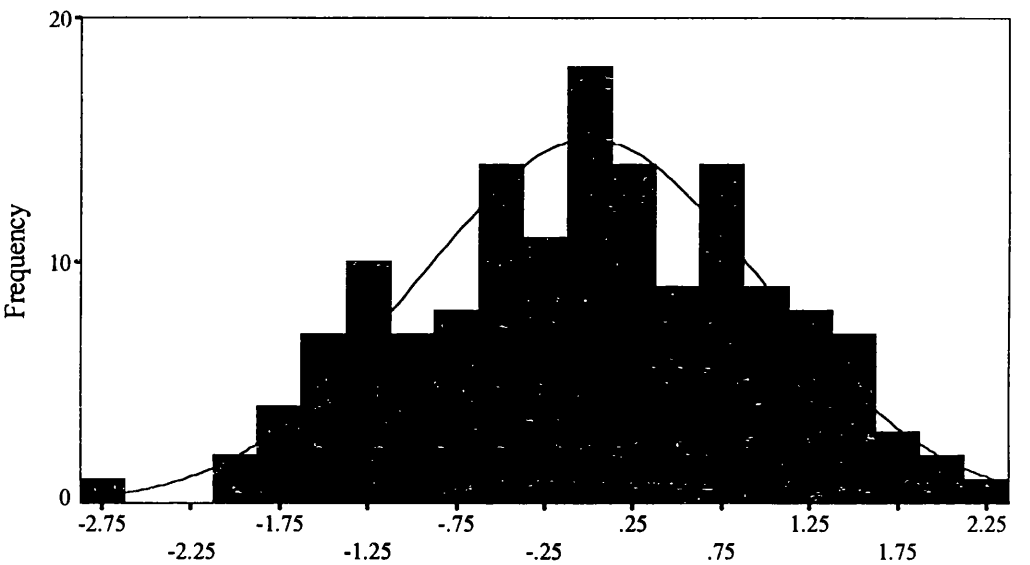
The SF-36-II mean score for each subject was computed by summing their scores over the individual domains and then dividing by the number of domains (eight). This average score was regressed against the average SF-36-I mean score (X_1), social network score (X_2), presence of diabetes mellitus (X_3) and current smoking status (X_4) to obtain

$$Mean(PhaseII) = 26.82 + 0.45X_1 + 0.64X_2 - 15.37X_3 - 8.99X_4 .$$

The regression analysis is based on 148 subjects and has an adjusted R^2 value of 26.1%. The p-values for the null hypotheses that the coefficients of the regression and the constant term are not significant are set out in the table below.

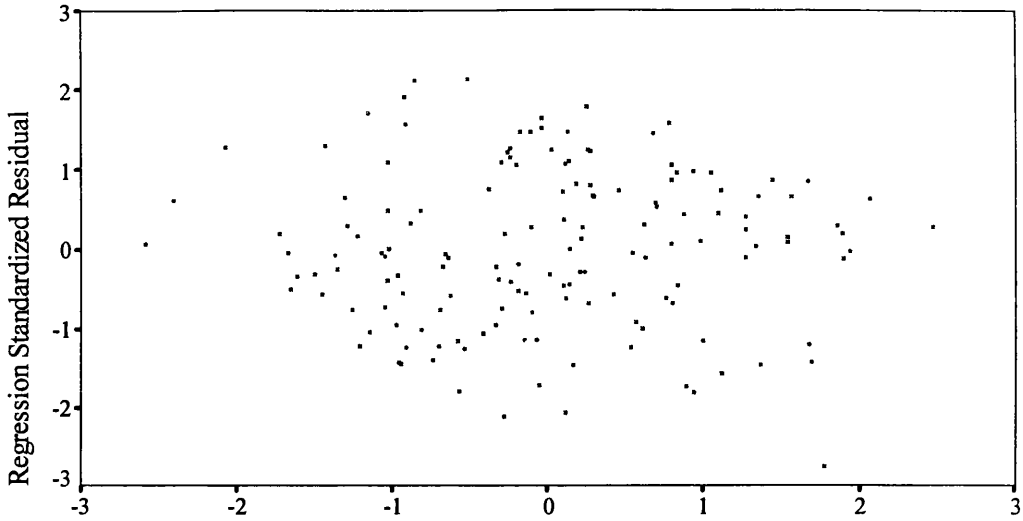
variables	constant	X_1	X_2	X_3	X_4
p-value	<0.001	<0.001	0.016	0.004	0.037

The analysis of the mean identifies the variables that make the most significant contributions to the overall SF-36-II domain structure The histogram of residuals and their scatter plot versus standardised predicted values are



Regression Standardized Residual for Mean SF-36 Domain Score (Phase II)

Scatterplot of dependent variable Mean SF score (Phase II)



Appendix XVII. Bivariate correlation* (Pearson) table of SF-36-II domains versus other phase II variables

Table A Bivariate correlation* (Pearson) table of SF-36-II domains versus other phase II variables

SF-36-II domains	Bodily Pain	Energy Vitality	General Health	Mental Health	Physical Function	Role: Emotional	Role: Physical	Social Function
age (yrs)	0.108 (176)	**0.149** (177)	**0.181** (178)	0.120 (177)	0.055 (178)	-0.005 (169)	0.072 (174)	0.140 (177)
age-onset (yrs)	0.136 (159)	**0.160** (160)	**0.190** (161)	0.108 (160)	0.080 (161)	0.080 (153)	0.111 (159)	**0.163** (160)
alcohol (units/week)	0.020 (153)	**-0.184** (152)	**-0.176** (153)	**-0.172** (152)	-0.089 (153)	-0.060 (146)	-0.028 (150)	-0.088 (152)
angina II (yes/no)	**-0.419** (177)	**-0.327** (178)	**-0.312** (179)	**-0.244** (178)	**-0.319** (179)	**-0.239** (169)	**-0.213** (175)	**-0.444** (178)
angina II (+ve)	**-0.520** (81)	**-0.497** (81)	**-0.597** (81)	**-0.285** (81)	**-0.594** (81)	-0.215 (77)	**-0.468** (80)	**-0.489** (80)
BMI-II	-0.064 (177)	-0.117 (178)	-0.038 (179)	-0.076 (178)	-0.118 (179)	-0.118 (169)	-0.116 (175)	-0.120 (178)
breath II (yes/no)	**-0.353** (177)	**-0.444** (178)	**-0.425** (179)	**-0.346** (178)	**-0.426** (169)	**-0.271** (169)	**-0.397** (175)	**-0.334** (178)
breath II (+ve)	**-0.315** (114)	**-0.403** (113)	**-0.503** (114)	**-0.205** (113)	**-0.567** (114)	**-0.319** (110)	**-0.493** (112)	**-0.425** (113)

* Significant correlations are indicated in bold

Table B. Bivariate correlation* (Pearson) table of SF-36-II domains versus other phase II variables

SF-36-II domains	Bodily Pain	Energy Vitality	General Health	Mental Health	Physical Function	Role: Emotional	Role: Physical	Social Function
Tchol II (mmol/l)	-0.092 (169)	-0.110 (168)	-0.023 (169)	-0.148 (168)	-0.115 (169)	-0.103 (160)	-0.051 (165)	-0.017 (168)
depcat	-0.037 (180)	**-0.196** (179)	-0.096 (180)	**-0.177** (179)	**-0.229** (180)	-0.084 (170)	**-0.163** (176)	**-0.155** (168)
DBP II (mm Hg)	0.026 (166)	-0.025 (167)	-0.002 (168)	0.020 (167)	-0.019 (168)	-0.020 (158)	-0.076 (164)	0.025 (167)
diabetes mellitus	-0.068 (180)	-0.006 (179)	**-0.159** (180)	-0.101 (179)	**-0.197** (180)	**-0.279** (170)	**-0.236** (176)	-0.090 (179)
HLOC II	**-0.216** (97)	**-0.278** (96)	**-0.277** (97)	-0.165 (96)	**-0.205** (97)	-0.151 (93)	**-0.232** (96)	**-0.290** (96)
risk II	-0.016 (155)	**-0.170** (156)	-0.099 (157)	**-0.196** (156)	-0.100 (157)	**-0.181** (148)	-0.122 (153)	-0.108 (156)
current smoker II	-0.066 (178)	**-0.160** (179)	-0.142 (180)	-0.125 (179)	-0.118 (180)	**-0.161** (170)	**-0.163** (176)	-0.114 (179)
past smoker II	-0.105 (178)	-0.125 (179)	-0.007 (180)	-0.063 (179)	-0.065 (180)	**-0.157** (170)	-0.119 (176)	-0.085 (179)
SOC II	**0.277** (131)	**0.196** (132)	**0.346** (133)	**0.233** (132)	**0.291** (133)	0.150 (127)	**0.212** (131)	**0.317** (132)
SBP II (mm Hg)	0.012 (166)	-0.079 (167)	-0.082 (168)	-0.068 (167)	-0.084 (168)	-0.094 (158)	-0.085 (164)	-0.075 (167)

* Significant correlations are indicated in bold

Appendix XVIII. Bivariate correlation* (Pearson) table of angina II and breathlessness II scores with phase I variables

Table C. Bivariate correlation* (Pearson) table of angina II (+ve) and breathlessness II (+ve) scores with SF-36-I domains * Significant correlations are indicated in bold

SF-36-I domain	angina II (+ve)	breath II (+ve)	SF-36-I domain	angina II (+ve)	breath II (+ve)
Bodily pain	**-0.383** (78)	**-0.242** (111)	Energy/ vitality	-0.107 (79)	**-0.220** (110)
General health	-0.178 (79)	-0.106 (110)	Mental health	**-0.246** (79)	-0.042 (104)
Physical function	-0.029 (79)	-0.151 (110)	Role: emotional	-0.145 (78)	-0.180 (109)
Role: physical	-0.070 (78)	0.009 (109)	Social function	**-0.232** (79)	**-0.237** (110)

Table D. Bivariate correlation* (Pearson) table of angina II (+ve) and breathlessness II (+ve) scores with non-SF-36-I phase I variables * Significant correlations are indicated in bold

variable	angina II (+ve)	Breath II (+ve)	variable	angina II (+ve)	breath II (+ve)
age (yrs)	-0.194 (81)	-0.049 (115)	age-at-onset (yrs)	-0.110 (73)	-0.153 (104)
alcohol I (units/week)	-0.013 (64)	0.118 (93)	angina I (yes/no)	-0.124 (80)	-0.112 (112)
Tchol I (mmol/l)	-0.074 (68)	0.048 (99)	breath I (yes/no)	0.041 (80)	0.094 (112)
angina I (+ve)	0.096 (78)	**0.204** (108)	breath I (+ve)	0.053 (73)	0.042 (104)
depcat	-0.024 (82)	0.098 (116)	waist I	0.159 (82)	0.122 (116)
DBP I (mm Hg)	0.087 (80)	0.095 (114)	SBP I (mm Hg)	0.010 (80)	0.079 (114)
HLOC I	-0.016 (70)	0.010 (98)	SOC I	-0.170 (73)	-0.182 (102)
past smoker I	-0.067 (82)	0.102 (116)	current smoker I	0.088 (82)	0.095 (116)
risk I	0.076 (69)	0.156 (100)	diabetes mellitus	0.053 (82)	**0.197** (116)

Table E. Bivariate correlation* (Pearson) table of angina II and breathlessness II self-rated scores with SF-36-I domains * Significant correlations are indicated in bold

SF-36-I domain	angina II	breath II	variable	angina II	breath II
Bodily pain	**-0.337** (174)	**-0.185** (174)	Energy/ Vitality	**-0.232** (172)	**-0.240** (172)
General health	-0.083 (173)	-0.121 (173)	Mental Health	**-0.295** (172)	**-0.255** (172)
Physical function	-0.144 (173)	**-0.180** (173)	Role: Emotional	-0.130 (172)	**-0.184** (172)
Role: physical	-0.062 (172)	-0.133 (172)	Social Function	**-0.254** (173)	**-0.157** (173)

Table F. Bivariate correlation* (Pearson) table of angina II and breathlessness II self-rated scores with non-SF-36-I phase I variables * Significant correlations are indicated in bold

Variable	angina II	breath II	variable	angina II	breath II
age (yrs)	**-0.190** (180)	**-0.156** (180)	age-at-onset (yrs)	-0.135 (164)	**-0.212** (164)
alcohol I (units/week)	-0.060 (155)	0.011 (155)	angina I	-0.006 (178)	0.096 (178)
Tchol I (mmol/l)	-0.128 (159)	-0.018 (159)	breath I	-0.011 (178)	0.120 (178)
depcat	-0.003 (182)	0.104 (182)	waist I	0.118 (182)	0.103 (182)
DBP I (mm Hg)	0.046 (179)	0.019 (179)	SBP I (mm Hg)	-0.042 (179)	-0.032 (179)
HLOC I	0.042 (154)	0.031 (154)	SOC I	**-0.163** (160)	**-0.272** (160)
past smoker I	0.010 (182)	-0.122 (182)	current smoker I	0.070 (182)	**0.167** (182)
risk I	0.002 (159)	0.085 (159)	diabetes mellitus	0.039 (182)	0.112 (182)