HOW THE EXPERIENCE OF LIVING WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR INFLUENCES THE EDUCATIONAL NEEDS AND CONCERNS OF PATIENTS AND THEIR PARTNERS

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Abstract

Background: The aim of this study was to develop an understanding of how the experience of living with an Implantable Cardioverter Defibrillator (ICD) influenced patients and their partners' educational needs and concerns. An ICD is a device that is designed to treat patients who have life-threatening arrhythmias. The quality of life (QoL) of the ICD recipient is not only influenced by the disease itself but by adjustment to an altered life situation. Providing patient education can be an effective intervention to improve patient adjustment to the device. However, there is little qualitative research on the educational needs and concerns of these patients. It is therefore argued that qualitative research focussing on the lived experiences of patients is needed to identify appropriate educational interventions to facilitate this adjustment.

Methodology: The constant comparative method of constructivist grounded theory was employed for data collection and analysis. Semi-structured face-to-face interviews were carried out with fourteen ICD patients and four partners.

Findings: A grounded theory model was developed which described how patient's experiences of getting back to normal following the insertion of an ICD influenced their educational needs and concerns and ultimately led to their acceptance of the ICD. The model had two key components, getting back to normal and being informed. How the patients and carers experienced getting back to normal consisted of adapting lifestyle, focusing on the positive, effect on the family and living with the uncertainty regarding experiencing an ICD shock. Their experience of the ICD influenced their educational needs in that the information needed to be tailored to their individual experiences.

Discussion: This study found a strong need to feel informed, which is a major part of Mishels theory of uncertainty. The model is also compared to the crisis theory and the common-sense model of illness representations. The chapter ends with a conclusion and recommendations for future research.

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Chapter 1

Introduction

Rationale for this study

A number of studies have reported improved rates of survival of patients who have had an ICD inserted (Moss et al. 2001; Maron et al. 2007; O'Mahony et al. 2012). However, while the ICD has enhanced survival, it has also produced a new population of patients distinct from the general cardiac population. The experience of the device shock is unique to patients with ICDs (Sears & Kirian, 2010). Furthermore, for those who have the ICD for secondary prevention, they have survived a life threatening event which could influence their outlook on life (Sears & Kirian, 2010). Whether the patient has had the ICD inserted for primary or secondary prevention they all have to learn to live with a device which may deliver an electrical shock unexpectedly at any time or place. Sears and Kirian (2010) assert that even now, over 30 years after the first ICD implantation, an ICD shock is still considered a critical event for patients.

The quality of life (QoL) of the ICD recipient is not only influenced by the underlying disease itself but by adjustment to an altered life situation. Dickerson et al. (2010) assert that the implantation of an ICD can, impact on their psychological well being and QoL and in some cases can contribute to the development of affective disorders such as depression and anxiety. This assertion is supported by Shea, (2004) who states that patients with ICDs often experience physical, emotional and psychosocial

needs idiosyncratic to their condition that can impact on their overall QoL. Dickerson et al. (2010) emphasises that ICD recipients must adjust to a lifestyle that may be considerably altered as a result of device implantation. It is widely acknowledged that the psychological and social consequences of ICD implantation are diverse however; the majority of current research has focused on mortality and morbidity (either mental or physical) outcomes. One meta-analysis carried out by Burke et al. (2003) identified that there was some degree of psychological maladjustment associated with the implantation of an ICD. They further identify that compared to other cardiac patients they scored lower on two QoL variables (psychological and physical functioning) suggesting that they had poorer QoL than other cardiac patients. However they acknowledge that the psychological maladjustment experienced by some of the patients with ICDs may be more to do with their underlying ventricular arrhythmia or the fact that some had experienced SCD rather than their ICD.

Frizelle, Lewin, Kaye and Moniz-Cook, (2006) identify that there has been little research on the educational needs and concerns of these patients. NICE (2006) has recommended that a rehabilitative approach to care, which includes psychological restitution for living with an ICD, should be implemented. A review carried out by Eads, Sears, Sotile and Conti, (2000) concluded that providing information and patient education early in the implantation process can be an effective primary intervention to

reduce patient concerns or to allay distress following an ICD shock. However it is argued that further research into identifying appropriate educational interventions to facilitate psychosocial adjustment of ICD patients is needed (Zayak & Finch, 2009).

Relevance to the Researcher

I developed an interest in the education patients receive following the diagnosis of a heart condition when I worked at the Centre for Cardiac Care and Education at the University of York.   During my time there I co-authored the Heart Failure Plan, a self management manual for patients with heart failure and their carers. Authoring this manual highlighted for me the importance of patients receiving sufficient education to enable them to cope with the diagnosis of and living with a heart condition. When I was identifying potential areas to research I spoke to a number of researchers both at the University of York and also at a Cardiac care and education conference. Through these discussions I ascertained that patients with ICDs were a population that had not been focussed on as much as those who had had a heart attack, angina, heart failure or coronary heart disease with regards to research studies or patient education.

Relevance to the Population

Prior to carrying out this research I spoke to a research nurse lead from Chest Heart and Stroke Scotland, regarding the education patients with implantable cardioverter defibrillators currently receive. The research nurse identified that the education patients with ICD was inadequate and not delivered in a consistent way. I therefore decided that I should carry out a study that focussed on the educational needs of patients with ICD's

The population in this study were all recruited from an ICD support group in Scotland. Unlike most support groups, this support group did not meet regularly (generally only meeting once a year), the main form of communication being through a newsletter. They also provide patient information sheets regarding living with the ICD which are given to every person who had an ICD implanted in Scotland. A full description of the support group is located in Chapter 5. This support group therefore was more about providing information than of providing face-to-face peer support. When I contacted the support group secretary regarding my proposed study he was very enthusiastic as, being a recipient of an ICD himself, he felt that the information he received following his ICD implantation did not meet the needs he had and while the support group now provided information to all ICD recipients in Scotland, he did not know if the information provided what was needed by the patients at that particular time. He therefore felt that my findings could help to inform the development of the information they provide to ICD recipients.

Aim of the Study

The aim of this study will be to develop an understanding of whether the experience of living with an ICD influences patients and their partners' educational needs and concerns.

Overview of this thesis

This thesis comprises of seven chapters.

Chapter one provides the rationale for the development of the study, a description of the technological development of ICD and a description of the patient population.

Chapters two and three comprise the literature review; chapter two providing a review of the literature relating to the biopsychosocial aspects of living with an ICD, chapter three focussing on patient education and support in patients with ICDs. While the main literature search and review was undertaken following the development of the grounded theory model, I have located the literature review at the start of the thesis, as to conform to the structure of the majority of theses.

Chapter four comprises the methodology chapter, outlining the grounded theory methodology and Chapter five outlines the method employed.

Chapter six comprises my research findings and outlines the grounded theory model developed.

Chapter seven, the discussion chapter, presents my findings in relation to earlier research studies and my conclusions and recommendations for the patient education materials provided to patients with ICDs.

Background

Coronary Heart Disease

Coronary Heart Disease (CHD), also known as Ischaemic Heart Disease (IHD), is caused by the build up of fatty materials (atheroma) in the blood vessels that supply the heart with oxygen (artherosclerosis) (Castelli, 2012; Willett, 2012). These blood vessels subsequently become narrowed. The main forms of CHD are myocardial Infarction (MI) and angina.

Scotland, compared to the rest of the UK, has a disproportionately high incidence and prevalence of CHD. Scarborough, Wickramasinghe, Bhatnagar and Rayner (2011) identified that, in Scotland, the premature mortality rates due to CHD is 25% higher than England. The Information and Statistics Division (ISD) (2011) identified that in Scotland in 2011-2012 there were 19,441 reported cases of heart disease; in addition

approximately 12,103 people had a heart attack in Scotland in 2011-2012.

Sudden Cardiac Death

The Scottish Intercollegiate Guidelines Network (SIGN) guideline, Cardiac Arrhythmias in Coronary Heart Disease (SIGN, 2007, reviewed and reaffirmed, 2011), identifies that 70% of Sudden Cardiac Death's (SCD's) are caused by coronary heart disease.

In the United Kingdom SCD, or sudden cardiac arrest (SCA), occurs in roughly 50,000-70,000 people per year. Myerburg and Castellanos (1997) cited in Priori et al. (2001) provide a concise definition of SCD, which is used by the European Society of Cardiology, identifying it as;

> Natural death due to cardiac causes, heralded by abrupt loss of consciousness within one hour of the onset of acute symptoms; pre-existing heart disease may have been known to be present, but the time and mode of death are unexpected. (Myerburg & Castellanos, 1997, cited in Priori et al. 2001 p3)

Buxton et al. (2006), identify that less than 5% of people survive from SCD. Buxton et al. assert that of those who do survive SCD, 15% will experience another SCD event within the following year, which, if untreated is usually fatal (Buxton et al. 2006). Of these deaths, Buxton et al. estimate that 80% are attributable to ventricular tachyarrhythmias, for example ventricular fibrillation (VF) and ventricular tachycardia (VT) with

the remaining 20% being attributable to other conditions such as bradychardia. Ventricular fibrillation (VF) is the most frequent rhythm recorded prior to SCD. Studies such as Gang et al. (2010) have reported that 75-80% of cases originate from this arrhythmia whereas in the remaining 15-20% a bradyarrhythmia, including asystole and complete atrioventricular block is recorded.

Prevention of ventricular tachyarrhythmias is either primary (preventing from happening) or secondary (preventing from recurring) and treatment is aimed at either suppressing or stopping the arrhythmia (Bryant, Brodin, Lovemann & Clegg, 2007). The main treatments are anti-arrhythmic drug therapy (AAD) which is the most common long term treatment, or the implantation of an Implantable Cardioverter Defibrillator (ICD).

The Implantable Cardioverter Defibrillator

An ICD is a device that is designed to treat patients who have life-threatening arrhythmias (NICE, 2006). The first ICD was implanted by Michel Mirowski in 1980 (Mirowski, Reid, Watkins, Weisfeldt, & Mower, 1981). Five years later the ICD was approved for human use (Sola & Bostwick, 2005). Early ICDs were only able to detect and defibrillate the heart when it is in ventricular fibrillation (VF) or rapid ventricular tachycardia (VT). However the current ICDs can also provide bradycardia pacing support and convert ventricular tachycardia by delivering a rapid burst of anti-tachycardia pacing (ATP) (NICE, 2006). By

constantly monitoring the patient's heart rhythm the device senses and corrects a disturbance in the rhythm (NICE, 2006). Since their introduction in the 1980's, ICDs have become a feasible treatment option for patients with sudden cardiac death (SCD), intolerant ventricular tachycardia and fibrillation or drug-resistant arrhythmias (Craney, Mandle, Monro, & Rankin, 1997, Buxton et al. 2003).

The NICE (2006) guidelines support this assertion, recommending that, for patients who have survived VF or VT with haemodynamic compromise, ICDs should be routinely considered for patients, for secondary prevention of arrhythmic death. They also recommend ICD therapy for primary prevention for those patients who have not as yet had a serious arrhythmic event; however they have been identified as being at high risk of SCD (NICE, 2006). This group consists mainly of patients who have survived an MI. These guidelines recommend the various categories of patients who should be considered for an ICD. These categories were:

1. The primary prevention of SCD in the group of individuals who can be identified as being at high risk of SCD either
   a. from a number of clinical factors (e.g. previous history of heart attack, heart failure and results of electrical testing of the heart)
   b. or in the presence of specific cardiac abnormalities known to carry a high risk of SCD including people with familial conditions such as long QT syndrome, and hypertrophic caridomyopathy as well

as certain types of congenital heart disease.
2. The secondary prevention of SCD in individuals who have survived (been resuscitated) a sudden cardiac event.

(NICE, 2006, p2)

The SIGN guidelines – Cardiac Arrhythmias in Coronary Heart Disease (SIGN, 2007) also recommend that patients in Scotland, who are either at risk of VF or VT (primary prevention) or who have survived life threatening arrhythmias (secondary prevention) should be considered for ICD insertion.

In 2008 approximately 120,000 patients received an ICD worldwide (Dickstein et al. 2008). In the United Kingdom in 2000, there were over 4000 patients with an ICD (Tagney, James & Albartan, 2000). This is an increase of over 3560 from 1996 (Tagney et al. 2000). Currently, in Scotland, there are only two centres which implant ICDs with an overall implant rate of approximately 13 per million (Scottish Executive, 2002). Table 1 below outlines the number of ICDs implanted in Scotland for the calendar year 2010.

Table 1: Number of ICDs Implanted in Scotland in 2010.

Procedure	Number of Patients
Cardioverter defibrillator introduced through the vein - (including removals and renewals)	**522**
• Implantation of cardioverter defibrillator using one electrode lead	121
• Implantation of cardioverter defibrillator using two electrode leads	131
• Implantation of cardioverter defibrillator using three electrode leads	27

Source: SMR01 ISD Scotland

NHS Scotland: Number of Patients with a Cardioverter defibrillator introduced/implanted in 2010.

The use of Prophylactic ICDs has increased steadily since the results of two clinical trials- the Multicentre Automatic Defibrillator Implantation Study (MADIT-II) (Moss et al. 1996) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) (Bardy et al. 2005) - showed that ICDs provide a mortality benefit when used for prevention.

The ICD has been found to be more successful for preventing arrhythmic death than antiarrhythmic drugs and is now the treatment of choice in high-risk patient populations (Dunbar et al. 2009). The first randomised prospective primary prevention trial, the Multicenter Automatic Defibrillator Implantation Trial (MADIT-I) (Moss et al. 1996) showed that ICDs were the more effective treatment for patients with remote myocardial infarction with low left ventricular ejection fraction than

conventional medical therapy. Since then a number of large randomized trials have shown the positive effect of ICD therapy, initially in survivors of life-threatening arrhythmias, (Connolly et al. 2000; Kuck, Cappato, Siebels, & Rüppel. 2000). The MADIT-II trial in 2001 was the first trial to show the prophylactic benefits of ICDS in patients with ischaemic cardiomyopathy (Moss, Fadl, Zareba, Cannom & Hall, 2001).

Summary

The ICD is an implanted life-saving device that is designed to treat patients who have life-threatening arrhythmias. The considerable increase in its use has produced a new population of patients distinct from the general cardiac population (Carroll & Hamilton, 2006). Whether the patient has had the ICD inserted for primary or secondary prevention, all have to learn to live with a device that may deliver an electrical shock unexpectedly at any time or place. ICD recipients must adjust to a lifestyle that may be considerably altered as a result of device implantation. Due to this, it is asserted that a rehabilitative approach to care, which includes psychological preparation for living with an ICD, should be implemented. It is therefore argued that further qualitative research focussing on the lived experiences of patients regarding how they adjust to the device is needed to identify appropriate preventative interventions to facilitate this adjustment. The following chapter therefore reviews the psychological, medical, nursing and associated health

literature that investigate the impact of the ICD on the patients and partners.

Chapter 2

Literature review: Living with the ICD

This chapter provides a review of the literature relating to the biospsychosocial aspects of living with an ICD. However, within the field of grounded theory research the role of the literature review is a controversial one and therefore before commencing with the review it is appropriate to consider the role the literature review has in a grounded theory study (Dunne, 2011).

Role of the literature in a grounded theory study

In a grounded theory study, the notion of avoiding conducting the literature review before analysing the data is well documented (e.g. Stern 1980; Strauss & Corbin 1994; Hickey 1997). They assert that by avoiding a literature review at the start of the study it is more probable that the theory that emerges will be 'grounded' in the data. Charmaz (2006) argues that while approaching a research study knowledge free is impossible, you should leave the actual literature review until after most or all of the research has been completed. However, as a doctoral research student, prior to starting the research study I was required to present a research proposal, which was to include a brief review of the literature. The dissertation is required to present a unique contribution to existing knowledge. Therefore, to identify an area where there was a lack

of knowledge, I had to determine the current state of knowledge. Subsequently, at the start of the study I carried out a limited review of the literature to identify existing knowledge, to provide a rationale for the proposed research and to inform the development of my interview schedule. Following a brief review, I identified that there was a scarcity of knowledge in the intended study area, which therefore provided me with the study rationale. This approach was advocated by Smith and Biley (1997) who state that:

> General reading of the literature maybe carried out to obtain a feel for the issues at work in the subject area, and identify any gaps to be filled in using grounded theory… but it is important that the reading is not too extensive. (Smith & Biley, 1997 p20)

The more extensive literature review was conducted following the analysis of my data to contextualise the findings within the existing literature.

Selection of studies for inclusion

Electronic databases were searched using the following key words and mesh terms relating to ICDs, experiences and patient education: ICD, implantable cardioverter defibrillator, implanted cardiac devices, adjustment, educational needs, educational concerns, patient education, psychosocial, psychological, "quality of life", support, experiences, beliefs, life situation, fears.

The following databases were searched from 1980-2012: Medline, Psychinfo, BNI, CINAHL, and CSI. Since the first ICD implant took place in 1980 it was unnecessary to search literature prior to this date.

The electronic search was supplemented by hand searching several relevant journals, including PACE: Pacing and Electrophysiology, Heart and Lung, and the Journal of Cardiovascular Nursing. The reference lists of identified articles were also reviewed to identify any relevant articles.

Evaluation of study quality

The quality of any review of research will depend on the quality of the included studies. Therefore, prior to the synthesis of research findings, a methodological evaluation of included studies was conducted. A quality analysis for the quantitative studies was performed according to the Effective Public Health Practice Project (EPHPP) (2009) Quality Assessment Tool for Quantitative Studies. The EPHPP is a tool that can be used to appraise a variety of quantitative intervention study designs including RCT's, before and after studies and case control studies.   The tool assesses 6 domains: 1) selection bias; 2) study design; 3) confounders; 4) blinding; 5) data collection method and 6) withdrawals/dropouts which are rated as either "strong" "moderate" or "weak".   Each study was assessed according to each of the six domains and the ratings of the criteria were aggregated with each study receiving

an overall quality assessment. In order for a study to be rated as "strong", four of the six domains had to be rated as strong, with no weak ratings. For the qualitative studies, Campbell et al. (2003) propose that, following a systematic search for papers, to screen out unsuitable papers and papers of poor quality an appraisal process should be carried out. The NHS guidance for systematic reviews highlights the need for a structured approach to quality assessment for qualitative studies (Dickson-Woods, 2007; Tong, Sainsbury and Craig, 2007). This review utilised the quality assessment criteria developed by the Public Health Resource Unit (2006) Critical Appraisal Skills Programme which uses ten questions to evaluate qualitative research (see appendix 1).

The goal of patient education is to ensure that the patient not only understands their current health status but that they are also able to make the right decisions regarding their own healthcare and make the necessary changes in their lifestyle so that they attain best possible health (Syx, 2008). For this patient education to be effective, Hoving et al. (2010) assert that health professionals need to be aware of the impact the illness has on a patient's lifestyle. This chapter, therefore, presents an outline of the current literature relating to patients with ICDs and their partners. To do this, I draw on the body of psychological, medical, nursing and associated health literature that investigate the impact of the ICD on the patients and partners.

There is a considerable body of research concerning living with the ICD and the following review integrates the findings of research conducted by doctors, nurses and psychologists. However, differences in the disciplines of the researchers as well as the research methodologies and data collection methods employed made this integration complex.

The following review, which is a combination of both the initial review and the second, more extensive review, reflects the typical issues that are discussed in the literature. The main issues discussed include – quality of life (QoL), device shocks, psychological implications, lifestyle implications, ICD concerns and social support. These issues generally overlap in the literature, with QoL studies frequently reporting on psychological and lifestyle implications as well as the impact of device shocks and consequently will overlap in this review.

Quality of life

With the number of patients eligible for ICDs increasing, Groeneveld, Matta, Suh, Yang and Shea (2007) assert that it is vital for physicians and the potential ICD recipients to have a clear understanding of the impact the ICD may have on their quality of life.

Defining quality of Life

Quality of life has been expressed as a vague and complex concept to define (Farquhar, 1995). Despite the popularity of QoL as an outcome measure in health research there is little consensus as to its definition and it is not utilised with much consistency (Wong 2010). Some researchers assert that QoL cannot be defined exactly (Mandzuk & McMillan, 2005; Taylor, Gibson & Franck, 2008). Numerous definitions of quality of life have however, been put forward, for example, Sears and Conti (2002) defined quality of life as a "Multidimensional health outcome in which biological, psychological, and social functioning are interdependent". The World Health Organisation QoL group (1994) provide a more in depth definition:

> Individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment. WHO, 1994, p43).

This definition reflects the belief that QoL refers to a perception that is embedded in a cultural, social, and environmental context. Therefore, as asserted by Meeberg (1993) quality of life cannot be merely used interchangeably with the terms "health status", "life satisfaction", or "well-being". Instead, Meeberg asserts it is a "multidimensional concept

incorporating the individual's perception of these and other aspects of life." (Meeberg, 1993, p34).

Effect of ICD on patient QoL

Early research into the psychological effects of ICD implantation recognised that patients who had received an ICD encountered significant social and psychological challenges following ICD implantation (Hegel, Griegel, Black, Goulden & Ozahowski 1997; Heller, Ormont, Lidagoster, Sciacca & Steinberg, 1998). Quality of life is identified as being a significant factor in successful ICD therapy (Kao, Friedmann & Thomas, 2010). A review of the early literature around quality of life and psychological functioning in patients with ICD's concluded that ICD shocks are associated with increased anxiety and depression and other associated psychological issues (Sears & Conti, 2002). However, Sears and Conti found that, while ICD implantation has been shown to impact negatively on QoL, QoL levels may improve to pre-implant levels at 1-year follow-up. A number of early studies employed quantitative measures to assess QoL in patients living with an ICD (Hermann et al. 1997; Duru et al. 2001; Kamphuis et al. 2003). However, due to the wide range of QoL measures utilised, comparative analyses of the findings proved problematic.

Like the early studies, more recent studies have generally employed quantitative methods to assess the effect of an ICD on QoL (Noyes et al.

2007; Passman et al. 2007; Carroll & Hamilton, 2005; Ketchell & MacLean, 2011). However, these later studies recognise a need to use standard instruments for assessing QoL in patients with an ICD (Noyes et al. 2007; Passman et al. 2007). Examples include Ferrans and Powers quality of life questionnaire (Cardiac Version), (Bainger & Fernsler, 1995; Hamilton & Carroll, 2004; Carroll & Hamilton, 2005), the medical outcomes study 36-item short form health survey (MOS SF-36) (Duru et al. 2001; Marshall, Ketchell & MacLean, 2011) or the medical outcomes study 12-item short form health survey (MOS SF-12) (Groenvald et al. 2007). Both the Multicentre Automatic Defibrillator Trial-II (MADIT-II) (Noyes, et al. 2009; Piotrowicz, et al. 2007), the Defibrillators in Nonischaemic Cardiomyopathy Treatment Evaluation Study (Passman, et al. 2007) and a study carried out by Groenveld et al. (2007) all utilised the MOS SF-12. Two of the studies (MADIT-II and the Defibrillators in Nonischaemic Cardiomyopathy Treatment Evaluation study) employed a randomised controlled trial methodology, comparing ICD recipients to patients having standard medical therapy. The MADIT-II looked at, the difference in QoL scores between patients who had an ICD inserted (n=742), versus those who had medical treatment only (n=490). No significant difference in QoL scores between the two groups was found. Passman et al. (2007) studied 458 patients, 227 of which were randomised into the ICD therapy group. They found that, like the MADIT-II trial, the implantation of the ICD itself did not significantly impact on a patients quality of life. Groeneveld et al. (2007) however, used the MOS

SF-12 to study the health related QoL in patients who had had an ICD inserted for primary prevention compared to secondary prevention. They found that there is no significant difference in QoL between patients who had the ICD inserted for primary prevention and those who had the ICD inserted for secondary prevention.

Other QoL measures employed (both General and ICD specific) include, the Health Utility Index (Noyes, et al. 2007), the Ferrans and Powers Quality of Life Index, Cardiac Version (QLI-CV) (Dickerson et al. 2010) and the EuroQol 5D (Groeneveld et al. 2007). While, in all of the studies ICD implantation was not found to impact on QoL, one variable was found in several studies to influence QoL, namely whether the patient had experienced a device shock (Jacq et al. 2009; Passman et al. 2007; Sears, Lewis, Kuhl & Conti 2005) .

Experience of device shock

As the experience of ICD shock is unique to ICD patients, there is a significant body of literature focussing on the psychological consequences of this (Carroll and Hamilton 2005; Kamphuis et al. 2003; Van Den Broek et al. 2008; Jacq et al. 2009). Van Ittersum et al. (2003) states that, while it could be argued that having an ICD would mean that the patients were less fearful than other cardiac patients the opposite has actually been found. An early study carried out by Lewin, Frizelle and

Kaye (2001) found that while specific fears such as sudden death from the cardiac condition were reduced, other fears such as the fear of impending firings by the device were now evident. Lewin et al. described this fear of impending firings as being unique to ICD patients as no other condition has the same type of unpredictability and fear associated with it.

It has been proposed that mood disturbance and low quality of life in the recipients of ICD's can be attributed to the unique nature of the ICD shock (Burke et al. 2003; Jacq et al. 2009). For example, the unpredictability and discomfort associated with the discharge has been found to lead to psychological distress and psychosocial adjustment problems. A study carried out by Carroll and Hamilton (2005) looked at QoL in a group who had received an ICD shock compared to a group who had not received an ICD shock during the first year. They found that those in the group who had experienced a shock had worse mental health and vitality scores on the Medical Outcomes Survey, Short Form-36 (MOS SF-36) and increased anxiety and psychologic distress. However, this study only had 53 participants, of which, only 16 experienced a device shock, therefore generalisability to the ICD population is limited. In addition, only 17 females participated in the study, of which only 3 experienced shocks, further limiting the generalisability of the study. The randomised controlled trial by Passman et al. (2007) identified that while there was no significant difference in the MOS SF-12 scores between the shocked and non-shocked ICD recipients; shocks

were associated with a reduction in the scores on the mental component of the MOS SF-12. A later similar study conducted by Jacq et al. (2009) supported these findings, identifying that the prevalence of depressive symptoms was significantly higher in ICD patients who had experienced a shock compared to those who had not experienced a shock; however when comparing the two groups in relation to a depressive disorder, there was no significant difference between them.

The evidence surrounding the impact of shocks on patient outcomes is not consistent, for example, a study carried out by Pedersen et al. (2005) found that shock is less impactful on QoL. They found that while patients who had experienced a shock scored higher on the ICD Patient Concerns Questionnaire, the only determinant of anxiety and depressive symptoms was found to be ICD concerns. They conclude that ICD concerns rather than the actual shocks received, place a patient at risk of psychological distress. This finding is partly supported by Kamphuis et al. (2003) who looked at the quality of life and psychological well-being in patients who did or did not experience defibrillator shocks in the first 12 months after ICD implantation. They compared the quality of life of 167 cardiac arrest survivors, classified into three main groups, those who had received an ICD and had been shocked, those who had received an ICD and not been shocked and those who had received another treatment. Their main finding was experiencing a shock did not significantly impact on a person's overall quality of life and there was no significant change in the

overall quality between 6 and 12 months post discharge in either the group who had experienced a shock or the group that had not. However, when looking at role limitations, a significant change over time was found between the groups. Those patients who had experienced shocks during both time spans expressed that they were more limited in their daily activities compared with the other groups. In addition, the study did not assess the impact of ICD complications, mobility (such as the effect of driving restrictions), social support or drug therapy, factors which have all been found to impact on quality of life.

Other studies have identified that only patients who have received 5 or more shocks were at risk of an adverse outcome (Irvine, 2002). This finding is supported by Passman et al. (2007) and von Kanel et al. (2011) who all found that the experience of at least 5 shocks was substantially associated with increased psychological distress (including anxiety) and decreased quality of life.

In addition to appropriate shocks, inappropriate shocks are also identified as a problem for a considerable number of patients (Sakhuja et al. 2009). Inappropriate shocks are defined by Sakhuja et al. (2009) as shock therapies delivered by an ICD for the treatment of nonventricular arrhythmias and comprise 12% to 30% of all shock therapies delivered. Inappropriate ICD shocks have been found to be associated with a decreased quality of life and increased mortality (Passman et al. 2007).

The association between inappropriate shock and mortality has generally thought to be due to the underlying arrhythmias (for example atrial fibrillation) thought to be responsible, however the exact cause has not fully been identified (Marcus et al. 2011).

Marcus et al. (2011) carried out a comparative study looking at the recollection of pain due to inappropriate shocks, versus the recollection of pain due to appropriate shocks (n=100). They found that those with a history of an inappropriate shock (n=17) recalled greater pain than those with a history of only appropriate shocks. In some cases those who had a history of inappropriate shocks had considered deactivation of the device. However, due to the fact that the study was restricted to a single practice in a teaching hospital there is limited generalisability. In addition, the time between last shock and the interview was not recorded and it is possible that the differences in time from shock to interview differed in the two groups, which could potentially affect the results.

Psychological implications

While there is considerable evidence regarding the psychological implications of and psychosocial adjustment to the ICD, this evidence is conflicting. Although many patients adapt to the device over time, some degree of psychological distress is experienced by up to 87% of patients, (Sola & Bostwick, 2005). Early studies have identified that mood

disturbances such as anxiety (Dunbar et al. 1999; Vlay et al. 1989) and depression (Sears and Conti, 2002) are prevalent in the ICD population. However, the research around anxiety and ICD's is inconclusive. While earlier studies, such as Hegel et al. (1997) and Keren, Aarons and Veltri (1991) using quantitative methods found that anxiety in the ICD population was higher than in the general population, however, both studies had small sample sizes therefore limiting generalisability.

There are a number of reasons to hypothesize that the prevalence of anxiety in ICD patients may be decreasing. The majority of early studies regarding the prevalence of psychological disturbances in ICD patients were generated from studies conducted well before the publication of the results from the MADIT II (Noyes et al. 2007; Noyes et al. 2009) and the Sudden Cardiac Death in Heart Failure Trial (SCDHeFT) (Bardy et al. 2005), and before the implementation of the American Heart Association/American College of Cardiology guidelines (Epstein et al. 2008) in the USA, the SIGN guidelines (SIGN, 2007) in Scotland and the NICE guidelines (NICE, 2006), all recommending ICD implantation for the primary prevention of sudden cardiac death. Therefore, the majority of patients now receiving an ICD never experienced a cardiac arrest or severe ventricular arrhythmia. As a result, there have been preliminary reports that the current prevalence of symptoms of psychological discomfort may be lower compared to earlier reports referring to patients

receiving an ICD for secondary prevention only (Bostwick & Sola, 2007; Pozuelo et al. 2009).

Sears and Conti (2002) state that, following insertion of the ICD, patients must cope with "both the stress of experiencing a life threatening arrhythmia and the challenge of adjusting to the ICD" (p489). Anxiety has been found to be common in ICD recipients, with increased symptoms of anxiety being experienced by around 24–87% of ICD recipients (Sears et al. 1999). In addition Sears et al. identified diagnostic rates for clinically significant anxiety disorders ranging from 13%-38%. The experience of ICD shocks is usually indentified as the reason for this anxiety; however its causal influence is also impacted by fact that the patient also has a life threatening cardiac condition (Sears & Conti, 2002). This assertion is expanded upon by Maryniak et al. (2007) who purport that anxiety disorders in the patients with frequent ICD discharges may possibly be due to two mechanisms, one of which being generalized anxiety. At first fear is focused on the ICD implantation and heart symptoms, which are constantly with the patient and consequently become permanent, turning into a chronic state. The second mechanism, Maryniak et al. (2007) asserts, is similar to classical conditioning, where the ICD shock becomes associated with the situation it occurs in, leading to circumstances being linked to experiencing pain and fear.

Post-traumatic stress disorder

The potential for post-traumatic stress disorder (PTSD) in cardiac patients is increasingly recognised (Ladwig et al. 2008). In ICD patients, studies have identified that the experience of an ICD shock is both unique to the ICD patient and can be perceived as a traumatic event (Sears et al. 2011). Furthermore, the existence of the associated heart disease, angina, heart failure or a SCD event, may produce sensitivity to traumatic stress (Sears et al. 2011). Nevertheless, in the ICD patient population PTSD has received less attention than anxiety and depression. However, von Kanel et al. (2011) purport that as the ICD therapy may act as a reminder that they are suffering from what could probably be a fatal disease. Therefore, patients with an ICD could be particularly disposed to suffer from PTSD. Von Kanel et al. (2011) carried out a quantitative questionnaire study looking at 107 consecutively enrolled patients which found that post-traumatic stress as evidenced by the Impact of Events Scale-Revised, increased from baseline (between 3 and 45 months after implantation) to follow up (between 23 and 59 months later). Specifically they found that patients who experienced five shocks or more during the follow-up period were significantly more likely to experience increased post-traumatic stress. However, the small sample size did not allow for inclusion of other variables for study, including coping style and social support, both of which have been found to predict PTSD.

Comparison to other cardiac populations

Given the uniqueness of ICD therapy; including the unpredictability of the device discharges, it seems probable that ICD patients would be more vulnerable than other cardiac patients to symptoms of psychological distress or declines in quality of life.   Several studies compared patients with ICD's to patients with permanent pacemakers; however few consistent differences could be established between these two populations (Duru et al. 2001; Leosdottir et al. 2006). For example, Duru et al. (2001) found no significant differences in QoL score, anxiety or depression when comparing ICD patients with and without shock experience and pacemaker patients. Leosdottir et al. (2006) also found no significant difference between pacemaker patients and ICD patients in with regards to psychological distress (p = .320), anxiety (p = .819) and depression (p = .121). Also, no significant difference was found between the ICD patients who had had a device shock and those who did not. However only 41 participants had ICDs and, of those, only 19 had experienced a device shock, therefore the fact that it is not statistically significant may be due to the small sample size.

Lifestyle implications

Beery, Bass, Matthews, Burroughs and Henthorn, (2005) identify that there is little known about how people adapt to living with an ICD, and

because of this have developed a scale which assesses how well a person had adjusted to living with an ICD; the Implanted Device Adjustment Scale (IDAS). The scale consisted of a 29 item questionnaire (although, due to a finding of weak item-to-total correlations on 9 of the items, only 20 of the questions were included in the analysis). The questionnaire was found to have high reliability (cronbach alpha of 0.9) and also high test-retest reliability (correlation of 0.92). The questionnaire focused on the following areas; attitude towards the device, body image, relief of symptoms and effective device function. The study found that the group who had pacemakers reported better adjustment than the patient group who had ICDs. This was irrespective of whether the ICD group had experienced a shock. However, due to the limited sample (final sample size being 27 people with ICDs), the findings have limited generalisability. It was therefore concluded that a larger sample size is needed to increase this generalisability and fully assess the psychometric properties of the questionnaire. A further study was carried out by Beery, Bass and Henthorn (2007) with a larger sample size of patients with either a pacemaker or an ICD (n=174). Unlike the earlier study, they found that while patients with an ICD were more fearful and/or anxious than patients with pacemaker only, no differences in total adjustment were seen between the two groups.

However, while there is little quantitative evidence identifying how ICD recipients adapt to life, there have been several qualitative studies

focussing on this issue. A study carried out by Williams, Young, Nikoletti and McRae (2007) found that participants adopted an approach to life in which they accepted living with the ICD and then incorporated it into their daily life, resulting in them in some cases forgetting it was there. This finding reflects that of Bolse et al. (2005) who described how participants adapted to living with the ICD and incorporated it into their daily life. A qualitative interview study carried out by Eckert et al. (2002) looked at how the ICD affects the life of patients and their families. They found that while each of the six participants (three ICD recipients and three partners) identified that there were subtle changes to their lifestyle following the ICD implantation generally these changes were manageable and did not adversely affect their lifestyle. However one particular change did affect their independence, namely the restriction imposed on their driving.

Driving restrictions

While most ICD recipients are ambulatory and appear well enough to drive a car, patients with ICDs have a constant threat of experiencing a shock causing sudden incapacitation (Vijgen et al. 2010). The issue regarding whether a patient with an ICD is fit to drive is a controversial one and there is little evidence regarding driving restrictions following ICD implantation or following the first appropriate or inappropriate shock (Kawata et al. 2010). The most recent UK guidelines regarding driving following an ICD implantation or ICD shock were published in 1997 and mainly related to patients who had an ICD for secondary preventative

reasons. However, with the growing numbers of patients implanted for primary prevention; guidelines are currently being developed that take into account the needs of this patient group.

Previously, in the UK, ICD recipients had a lifetime ban from driving and it has only been recently that regulations have been relaxed. Now, ICD recipients may be allowed to drive between one and six months following implantation. However this is dependent on individual circumstances (Driver and Vehicle Licensing Agency (DVLA), 2012). The DVLA state that following any adjustments to the device, ICD recipients were not allowed to drive for one month. Having a driving restriction imposed has been found to negatively affect the ICD recipients and their families' daily life (Johansson & Stromberg, 2010).

Sexual activity

While patient's anxieties fears and concerns have been well studied, their sexual concerns are not well understood and little research has been carried out focussing on this issue (Vazquez et al. 2010). Generally, the information patients receive following implantation of the ICD includes information regarding returning to earlier activity levels. However, there is reluctance among health professionals to address sexual issues (Steinke, 2003). Steinke (2003) carried out a study focussing on the reported sexual activity of patients following ICD implantation (n=82) and partners (n=47). They found that reduced interest was reported in 29% of patients

(n=20). Early studies looking at the reasons for decreased sexual activity post-ICD implantation, found that as well as fear of shock, other reasons included, changes in body image and that no information on resuming sexual activity had been provided by the health professionals (James, 1997; Sneed et al. 1992). Generally, ICD recipients and their partners want to resume normal sexual activity, with some experiencing increased interest (Steinke, 2003). However other studies report that patients experience periods of decreased interest in sexual activity and decreased libido (Williams et al. 2007). In addition, it has been reported by Zayak et al. (2009) that patients and partners fear that engaging in normal sexual activity could result in a shock. Albarran et al. (2004) also reported that patients' fear that sexual activity could result in a device shock was the main reason for abstaining from sexual activity.

Physical and social activity

A study carried out by Flemme, Hallberg, Johansson and Stromberg (2011) found that patients felt exhausted at the end of a day and lacked the energy to engage in social activities. Some studies for example Dougherty, Benoleil and Bellin (2000) identified that over 50% of ICD recipients did not return to work. While some saw this as a negative thing, a qualitative study carried out by Williams et al. (2007) identified that some patients viewed it as an opportunity to engage in other activities they had no time to do before.

ICD-related fears and concerns

Fears and concerns regarding the ICD; particularly fears regarding the device discharging, are common and have been identified as a major influencing factor in the experience of psychological distress, decreased quality of life, and the extent to the ICD implantation is experienced as a positive one (Dickerson, 2002). In addition, studies such as Sowell, Sears Walker, Kuhl and Conti (2007) and Pedersen et al (2004) have both highlighted that partners of ICD patients also experience fears and concerns regarding the ICD.

Uncertainty has been described as a major concern for patients with ICDs (Flemme et al. 2011). In fact Flemme et al. (2011) assert that "uncertainty regarding illness has been identified as the single greatest psychologic stressor for an ICD recipient with a life-threatening disease and/or arrhythmia" (p387). Mishel (1990) put forward the theory of illness uncertainty (IU) as a way of making sense of adjustment to acute and chronic illness. She asserts that uncertainty occurs in situations where; either due to lack of information the event cannot be defined or categorized sufficiently, the stimulus is perceived as being unclear or the classification of the situation is hampered, and the individual is unable to form a cognitive structure (Mishel, 1990).

Uncertainty has been linked to problems regarding psychosocial adjustment and a decreased quality of life (Mauro, 2008a, 2008b, Sossong, 2007).   In a study carried out by Flemme et al. (2005) uncertainly was found to be related to poor QoL in ICD recipients. However, their study found that while initially and during the first year there was a high degree of uncertainty, this uncertainty decreased over time. They hypothesise that, for ICD recipients, the first year may be the most uncertain phase, as they have not yet adapted to their changed situation.   A later qualitative, grounded theory study carried out by Flemme et al. (2011) found that a main concern for ICD recipients is uncertainty in daily life. To handle this concern, individuals incorporate this uncertainty into their daily lives by utilising the following strategies: restricting activities, accepting being an ICD recipient, distracting oneself, and re-evaluating life. Individuals utilise these strategies either one at a time or in combinations. One of the main findings in the study was that having a supportive network (social and professional) helped to facilitate the process of incorporating this uncertainty into their lives.

Social support

Social support has been defined as the presence of others, or the assistance and resources provided by them, during times of stress and is identified as a main defence against psychological distress (Langford, Bowsher, Maloney & Lillis, 2009). Deaton et al. (2003) found that ICD

recipients expressed a need for family and social support. Additionally, Deaton et al. emphasised that the spouse's supporting role is deemed crucial to patient adjustment. However, while a lack of social support has been identified as a determinant of anxiety and subsequent poor adjustment to the ICD, (Pedersen, Spindler, Erdman & Denollet, 2009) few studies have focussed specifically on the role of social support in patients with ICDs.

Conclusion

The review of the literature relating to ICD implantation has revealed extensive (and in some cases conflicting) evidence about how the ICD impacts on a patient's quality of life and the corresponding social, physical and psychological problems. A number of studies identified that the ICD negatively impacted on QoL (Sears and Conti, 2002; Carroll and Hamilton, 2005; Sola and Bostwick, 2005); however, others found that there was no significant impact on QoL (Passman et al. 2005; Groenveld et al. 2007). The impact of the ICD shock was a main focus of a number of research studies, however again results proved conflicting. While some studies found that the experience of a device shock impacted negatively on a patient's quality of life or psychological health, other studies found little evidence to support this assertion. While the QoL studies exclusively utilised quantitative measures, studies focussing on adaption to the changed life situation and the patient experience of living

with the ICD have generally employed qualitative methods. These studies found that patients generally adapt well to the changed life situation, however, in some cases the restriction regarding driving, concerns regarding sexual activity and dealing with the uncertainty around experiencing a device shock were all found to impact on how the patient adapted to living with the ICD.

The following chapter will focus on how health professionals support and educate patients regarding living with the ICD and the impact the ICD may have on their life and subsequent quality of life.

Chapter 3

Literature review:

The Education and Support of Patients with ICDs

The previous chapter described the experiences of patients with ICD's and the effect an ICD can have on a person's quality of life. When reporting on the experiences of patients with ICD's a number of studies have identified the need for support and education to improve their quality of life, reduce fears and concerns and minimise the effect of shocks on wellbeing (Morken, Severinsson & Karlsen, 2009; Noyes et al. 2007; Noyes et al. 2009). Sears, Matchett and Conti, (2009) assert that, to reduce mortality and morbidity, ICD patient management needs to include both medical and psychosocial care. The following chapter looks at how patients with an ICD are currently supported and educated.

Sufficient patient education improves the chances of patient engagement, psychosocial adjustment to the device and improved quality of life. However, two studies have identified that the current information provided to ICD recipients is insufficient for patients needs (Albarran et al. 2004, Strachan et al. 2011). Achieving good quality of life outcomes for ICD patients "begins with the communication of risk of cardiac arrest and the potential protective value of the ICD" (Sears et al. 2009, p1299). This doctor-patient discussion, which includes a discussion around the advantages and disadvantages of the ICD and the final patient decision,

starts the process of psychosocial adjustment for the patient and family (Sears et al. 2009).

Sears, et al. (2009) and Frizelle, et al. (2004) both assert that the majority of ICD patients are able to attain the desired quality of life and psychosocial outcomes. Sears, et al. (2009) however highlight that critical events, for example ICD shocks, if not properly managed, could dramatically impact on the whether or not the patient successfully adjusts to the device. Patient management support that attends these critical events as they occur could potentially improve patient adjustment to the device and facilitate the return to best possible daily functioning.

Generally studies looking at the education and support of patients with ICD's have employed quantitative measures, including randomised controlled trials; for example, Irvine et al. (2011) and Pedersen, Spek et al (2009). However one study carried out by Berg, et al. (2011) employed a mixed methods design utilising both quantitative (RCT) and qualitative (phenomenological interview) methods. The qualitative methods were employed to evaluate the intervention from the patient's perspective, and by moving beyond the statistical results explore the participant's views in more depth. They found that participation in the COPE-ICD programme inspired the participants to move on with their lives. This was due to the individualised care they received.

Cardiac rehabilitation

Cardiac rehabilitation (CR) is described by the Bethell, Lewin and Dalal (2009) as a multifactoral intervention. They identify that most cardiac rehabilitation programmes are generally outpatient, hospital-based and mainly focus on low-risk patients who have had an MI. However, some also include patients who have had coronary artery bypass surgery (CABG) or angioplasty. Furthermore, cardiac surgical interventions, such as percutaneous techniques are becoming more available to patients and therefore, the numbers who can potentially benefit from cardiac rehabilitation are increasing (Williams et al. 2006). The SIGN Guidelines (2007) recommend that ICD patients may benefit from participation in a cardiac rehabilitation programme, however they state that further research in this area is needed.

A meta-analysis carried out by the NHS Centre for Reviews and Dissemination (1998) has shown a 20%–25% reduction in SCD in post-myocardial infarction (MI) patients attending CR. However, whether these benefits are produced by exercise, improved secondary prevention or through psychobiological pathways has still to be determined. Patients who have been implanted with an ICD generally have coronary artery disease, heart failure or another underlying heart condition and would therefore have similar educational needs as other cardiac patients. Another aim of cardiac rehabilitation is to help the patients to adjust

psychologically to a heart attack, and to identify and treat and psychological disturbance.   Frizelle, Lewin, Kaye, Hargreaves et al. (2004) assert that, in this area, patients with an ICD would also benefit.

Frizelle Lewin and Kaye (2004) looked at the provision of rehabilitation services to patients with an ICD in the 39 NHS centres providing ICD implantation in the UK. Of the responses, 99% (from a sample of n=79) believed that rehabilitation should be provided to their ICD patients; however, 74% believed that ICD patient's rehabilitation needs were being met. Only 36% of the centres provided rehabilitation that ICD patients were able to access and only 10% of these (4 UK centres) provided rehabilitation service specifically for ICD patients. Several barriers to providing an ICD rehabilitation service were identified including lack of skilled multidisciplinary staff available to provide the service and the travelling distance for some patients to access the service. A study carried out by Frizelle, Lewin, Kaye, Hargreaves et al. (2004) looked at determining the effectiveness of a comprehensive CR programme for ICD patients. The programme incorporated both psychological and exercise-based components and found that following the intervention there was a significant reduction in anxiety ($p < .001$) and depression ($p < .005$) and a significant increase in quality of life scores ($p < .001$). However, although the participants were said not to differ from total ICD patient population, and therefore representative of the total ICD cohort, the small sample size (n=22) and subsequent small intervention group (n=12) potentially

limits the generalisability of the study.   They also did not evaluate the effects of the intervention over time, therefore, whether these benefits are sustained over time have not been determined.

Behavioural and/or psychosocial Interventions

In the past twenty five years, several behavioral and/or psychosocial interventions intended to improve psychological well-being in patients with ICDs have been developed, and preliminary evidence of a positive effect has been shown in small studies published in the past fifteen years. These have included interventions such as patient counselling and support groups (Fitchett, 2003).   While the majority of the studies reported subjective improvements for example improved psychological well-being (i.e. reduction in levels of anxiety and depression), improved psychological adjustment and enhanced quality of life (Sears et al. 2007; Crossmann et al. 2010), in one study this improvement did not reach significance (Chevalier et al. 2005).

Few studies involved a family member of the ICD recipient. One recent study that did was a brief educational intervention developed by Edelman, Lemon and Kirkness (2007).   However no significant improvement in anxiety levels or depression was found either immediately following the intervention or at 6-month follow-up. As it was a small sample size, they hypothesise that a larger sample size may identify improvement following

the intervention. Furthermore they do not appear to have studied the effects of the intervention on anxiety levels in the family member, and given that other studies have identified that partners of ICD recipients are also affected by their partners ICD it would therefore be useful to evaluate the effects of education and support on partners and family members. For example a grounded theory study carried out by Dougherty et al. (2004) found that partners experience increased mental exhaustion due to the increased responsibility they have in caring for their partner.

Cognitive behavioural therapy

Cognitive behavioural therapy delivered by a psychologist has been shown to benefit ICD patients by facilitating psychosocial adjustment to the device (Bostwick & Sola, 2007). A number of studies included cognitive behavioural therapy as either the only intervention (Kohn, Petrucci, Beassler, Soto & Movsowitz, 2006, Irvine et al. 2011), or in combination with cardiac rehabilitation (Fitchet, et al. 2003; Frizelle, Lewin, Kaye, Hargreaves et al. 2004; Lewin, Coulton, Frizelle, Kaye, & Cox, 2009). Kohn et al. (2006) conducted a prospective randomized controlled trial of individual cognitive-behavioural intervention with ICD patients. They identified that, following the CBT intervention; patients displayed decreased depression and anxiety. Also, when compared to those who had not had the intervention, patients who had had the intervention showed better overall adjustment to living with the device.

This was especially evident in the patients who had experienced an ICD discharge. A more recent study by Fitchet et al. (2003) found that a comprehensive 12-week cardiac rehabilitation programme lead to lower psychological distress levels and improved exercising ability. However the work has not been replicated.

Management of shocks

Interventions employing a CBT approach to reduce ICD shocks have also been developed. For example, a pilot trial carried out by Chevalier, et al. (2005) evaluated the effectiveness of a small group CBT intervention versus usual medical care. While the results were not statistically significant, possibly due to the small sample size, they did find that the number of patients requiring shocks was less in the CBT group versus the usual medical care group. However this difference was only found at 3 months following the intervention, by 12 months no difference was found. A few studies have looked at the management of the impact shocks in patients with an ICD. One study focussed on an ICD shock and stress management program (ICD-SSMP) (Sears et al. 2007). The aim of the intervention was to reduce "psychological and physiological markers of anxiety" and improve QoL in ICD patients who had a history of ICD shock (Sears et al. 2007, p858). The intervention was delivered in two different workshop formats – either six-weeks or one-day. They demonstrated that, following the six-week programme and the one-day workshop, there was a statistically significant reduction in both anxiety

levels and cortisol levels. Both programmes generated a significant increase in ICD acceptance by the patient. However, no significant change was found in the levels of depression. This was the first study that used both biological and psychological markers of anxiety to assess the outcomes of a psychosocial intervention in ICD patients who had experienced a shock. The study also employed outcome measures specific to patients with ICD's namely device acceptance. Device acceptance is a construct that measures patient adjustment to the ICD via the Florida Patient Acceptance Survey (FPAS). Sears et al. (2007) assert that the FPAS is a more sensitive measure of post-device functioning than a generic quality of life measure or measure of psychological adjustment.

A similar study carried out by Chevalier et al. (2006) looked to identify whether CBT resulted in a decrease of ventricular arrhythmic events needing ICD intervention through an improvement in sympathovagal balance. As psychological stress is known to trigger these events, they argued that by helping the patient to effectively manage their stress the number of shocks may be reduced. However, although they found that the group who had underwent CBT required less shocks; this difference was not statistically significant.

While the majority of interventions were delivered face-to-face, either individually or in a group, a few interventions utilised other delivery

methods, namely a web-based intervention (Pedersen, Spek et al. 2009), a computerised intervention (Kuhl, Sears, Vazquez and Conti (2009) or a telephone intervention (Dougherty, Thompson and Lewis, 2005). Pedersen, Spek et al. (2009) developed a web-based behavioural intervention the aim of which was to reduce anxiety and ICD related concerns and improve quality of life. However it has yet to be evaluated. A computerised education intervention was developed by Dougherty et al. (2011) which consisted of a CD-ROM psychoeducational CBT intervention (PACER) including topics on device functioning, mood, coping and relationships. The aim of the study was to examine whether the intervention improved device knowledge, patient acceptance of the device and QoL. The intervention group outcomes were compared to a usual care group and to an earlier study carried out by Sears et al. (2007) which utilised the same intervention but in an in person format. While no significant difference was found between the intervention group and the usual care group on ICD knowledge, QoL or device acceptance, of the patients who did demonstrate an increase in learning, there was a significant increase in acceptance of the device. Furthermore, compared with the previous intervention study, the participants in the PACER intervention were more likely to show an increase in knowledge.

An eight-week telephone intervention was developed by Dougherty et al. (2005) which aimed to increase physical functioning, psychosocial adjustment and self efficacy in managing the challenges of recovery and

also to reduce health care utilisation by ICD recipients. They found that when compared to usual care, the patients who participated in the intervention showed significant reductions in anxiety (p = .04), physical concerns (p = .006) and fear of dying (p = .01). Participants also showed improved self-confidence (p = 0.04) and increased knowledge regarding how to manage their recovery (p = .001). These benefits were sustained over a 12 month period. They however did not find any significant difference in health care utilisation over this period. Moreover, the intervention was only delivered to patients who had their ICD for secondary prevention, and they acknowledge that it may not be as effective for patients who receive an ICD for primary prevention of SCD.

Conclusion

This chapter described the various ways in which ICD recipients are currently supported. The majority of the studies identified employed cardiac rehabilitation and/or CBT as the main intervention and were generally delivered face-to-face. The majority of the studies focussed on how patients adjust to living with the device, using for example quality of life, levels of anxiety and or depression and psychological adjustment as the main outcome measures. All reported subjective improvements in the outcome measures; however, in some this improvement did not reach statistical significance. Only one study utilised qualitative measures to

study patient's experience of participation in an ICD specific rehabilitation programme.

The following chapters will outline the theoretical framework and the methods employed to explore the educational needs and concerns of patients with an ICD and their partners.

Chapter 4

Research Methodology

In this chapter I introduce and justify the overall methodological approach of this grounded theory study of how the experience of living with an ICD influences the educational needs and concerns of patients and their partners.

The research question guiding this study is:

- Does the experience of living with an ICD influence the educational needs and concerns of patients and their partners?

Selection of a qualitative research framework

I have selected a qualitative research framework. Following the guidelines set out by Denzin and Lincoln (2011), my own feelings and beliefs regarding the world and the way we should examine it influenced the choice of research paradigm and determined the research strategies and methods for this study.

Given that the term 'qualitative research' is not always used consistently and covers a wide range of definitions, it is worth starting with a definition. Qualitative research is described by Denzin and Lincoln (2011) as an approach:

> …that locates the observer in the world. It consists of interpretive material practices that make the world visible. These practices transform the world. They turn the world into a series of representations, including field notes, interviews, conversations, photographs, recordings and memos to the self. At this level qualitative research involves an interpretive, naturalistic, approach to the world. This means that qualitative researchers study things in their natural settings, attempting to make sense of […] phenomena in terms of the meanings people give to them (Denzin & Lincoln, 2011, p3)

The use of a qualitative approach in this study enabled me to explore the meanings the participants ascribed to their ICD insertion, from their perspective. As well as the importance of meaning, the approach addressed the importance of context and process, within the participants' experience of living with the ICD. These aspects would not have been components of the research if a quantitative approach had been used. Strengths of qualitative research approaches include their ability to provide intricate textual descriptions of how individuals experience a given research issue, with the potential for rich understandings of the studied phenomenon.

When choosing a qualitative research methodology, Creswell (2008) asserts that researchers must have a convincing justification. Creswell puts forward three reasons for choosing qualitative research, namely, the nature of the research question, the amount of research that has already been carried out on the topic area, and finally that the aims of the research corroborate the use of a qualitative research framework. I will

use these three reasons as a framework for justifying the use of qualitative research.

Nature of the research question

The question influencing this study is both open ended and exploratory. The main focus of my study was to look at the educational needs and concerns of patients with ICDs and their partners. To do this I needed to gain an insight into the lived experiences of the patients and partners. As Avis (2005) asserts, "qualitative researchers usually start with research questions that ask how we can acquire an understanding of social behaviour by exploring people's subjective accounts of social life" (Avis, 2005, p4). As educational needs are part of social behaviour, this is the focus of my research study.

Existing research

While there has been considerable research looking at the lifestyle implications of the ICD, there has been little qualitative research carried out to date regarding the educational needs and concerns of patients with ICDs and this study aims to go some way towards addressing this.

Aim of the research

The aim of my current research was to achieve a deep understanding of the experience of patients with ICDs and their partners and how this influences their educational needs and concerns. This matches the aims

of qualitative research, which according to Ritchie and Lewis (2003) are, "to gain an understanding of the nature and form of phenomena, to unpack meanings, to develop explanations or to generate ideas, concepts and theories" (Ritchie and Lewis, 2003, p82). Ashworth (2003); cited in Ridley (2004) proposes that the aim of qualitative research is to "elucidate the meaning of a situation or entity in terms of how it is perceived by the individual person" (p.93).   This also corresponds with the aims of my current study.

Selection of grounded theory

Qualitative research offers various methods of investigation, yet researchers are unable to agree how these should be to categorised. Wolcott (2001), puts forward 19 categories, whilst Tesch (1990) advocates as many as 26. However, Creswell (2012) only identifies five approaches: Phenomenology, Narrative research, Ethnography, Case studies and Grounded Theory.   The present study was based on qualitative data collection and qualitative analyses, using a grounded theory approach. The four approaches put forward by Creswell will be briefly summarised and the reasons for not selecting the approach for this study will be outlined.

Phenomenology

Phenomenology is defined as the study of experience from the perspective of the individual (Denzin and Lincoln, 2011). The focus of phenomenological research is to describe, rather than explain individual experiences. Cohen states that phenomenology is most useful when the "task at hand is to understand an experience as it is understood by those who are having it" (Cohen, 2000, p3).

There have been several phenomenological studies undertaken that focus on the lived experiences of patients with an ICD, for example Eckert and Jones (2002), Johansson and Stromberg (2010), Palacios-Ceña, (2011) and Berg et al. (2011). Phenomenology aims to describe the experiences of the participants, for example Johansson and Stromberg (2010) looked at the experiences of driving restrictions and Berg et al looked at the patient experience of participation in an ICD specific rehabilitation programme. This current study however sought to move beyond solely describing the experiences of patients with ICDs and their partners and instead look to understand how these experiences influenced their informational needs and concerns.

Narrative research

Squire, Andrews and Tamboukou. (2008) assert that the definition of narrative research is in dispute. Put simply, narrative research is research looking at stories. Squire et al. (2008) describe narrative research as a

"multi-level, interdisciplinary field" (p12). The intent of narrative analysis is the "search for and analysis of stories that people employ to understand their lives and the world around them" (Bryman, 2004, p412). However, rather than solely look at how people understand living with an ICD; this study aims to look at how their experience of living with an ICD influences their educational needs and concerns. I was unable to identify any ICD studies employing a narrative research methodology.

Ethnography

Ethnography is defined by Creswell as "a description and interpretation of a cultural or social group or system" (1998, p58). It is a multimethod form of research and is characterised by gathering data from a range of resources including observation, interviews, and documents (Runswick-Cole, 2011). A recent study carried out by Kaufman, Mueller, Ottenberg and Koenig utilised ethnographic case studies to "explore the complex cultural role of technology in American medicine today" (Kaufman, et al. 2010, p6). Although both grounded theorists and ethnographers share the same purpose, namely to carry out a rich study regarding a real life phenomenon, there are several differences. The principal aim of grounded theory is to generate theory that describes basic psychosocial phenomena and to understand how human beings use social interaction to define their reality (Glaser & Strauss, 1967) whereas the primary goal of ethnography is to provide an in depth account of the cultural phenomenon under study. Rather than providing an account of living

with an ICD, the aim of this study is to develop an understanding of how the experience of living with an ICD influenced patients and their partners educational needs and concerns. Therefore in this study, grounded theory is the most suitable methodology.

Case studies

Like grounded theory, the case study methodology is focussed on predicting, understanding and/or explaining human behaviour. A case study looks to encapsulate the complexity of a single case. Case study methodology is utilised not only in the social sciences, but also in the fields of medicine, environmental studies, social work, education, and business studies. There are diverse ideas regarding what a case study is (Flyvbjerg, 2005). According to Yin (2009) a case study design can be employed when 1) the focus of the study is "how" and "why", descriptive questions rather than "what" questions; 2) the researcher has no control over the behaviour of those involved in the study; 3) the phenomenon under study is in a real life context. I was unable to identify any studies that utilised the case study methodology.

This current study aims to move beyond in depth exploration of a situation, and instead try to understand how the experience of living with an ICD influenced patients and their partners' educational needs and concerns.

The Grounded Theory Method

The objective of a grounded theory study is to create or uncover a substantive or formal theory, and thus a means of explaining social processes. According to Stern (1995) "[...] the strongest case for the use of grounded theory is in investigations of relatively uncharted water, or to gain a fresh perspective in a familiar situation." (p30). Glaser and Strauss designed the methodology so that the researcher could uncover a theory "suited to its supposed uses" (Glaser and Strauss, 1967, p3). These assertions are supported by Locke who states that grounded theory is a useful method for generating theory where there is little already known as it "adapts well to capturing the complexities of the context in which the action unfolds…" (Locke, 2001, p95) Essentially, grounded theory research is a "method for discovering theories, concepts, hypotheses, and propositions directly from data rather than from a priori assumptions, other research, or existing theoretical frameworks" (Taylor & Bogdan 1998 p137). As I was looking at experiences and how they influenced the educational needs a patient with an ICD had, I felt that an inductive rather than a deductive approach was more suitable. More specifically, while there is substantial literature around how the ICD impacts on quality of life and psychological well being there is a paucity of research looking at the educational needs and concerns, of patient with ICDs therefore a grounded theory approach was identified as the most suitable methodology to employ.

Origins of grounded theory

Grounded theory was first formulated by Glaser and Strauss (1965, 1967). It is said to have developed from a combination of sociology and nursing. Glaser and Strauss's original research focussed on dying and resulted in two texts, Awareness of Dying (Glaser and Strauss, 1965) and Time for Dying (Glaser and Strauss 1968). Glaser and Strauss (1965) regard grounded theory as a general theory of scientific method that focuses on the creation, elaboration, and corroboration of social science theory. The basis of this method is an iterative inductive and deductive cycle where theory emerges from the data and is finally tested (grounded) against the real world (Glaser and Strauss, 1967). Strauss describes the purpose of grounded theory as being to organise "many ideas from the analysis of data" (Glaser and Strauss, 1967, p23). Charmaz, states that Glaser and Strauss's work was seen as groundbreaking, mainly because

> It challenged (a) arbitrary divisions between theory and research, (b) views of qualitative research as primarily a precursor to more "rigorous" quantitative methods (c) claims that the quest for rigor made qualitative research illegitimate, (d) beliefs that qualitative methods are impressionable and unsystematic, (e) separation of data collection and analysis, and (f) assumptions that qualitative research could produce only descriptive case studies rather than theory development. (Charmaz, 2000, p511)

According to Bryant and Charmaz (2007), within the social sciences, grounded theory is one of the most commonly utilised qualitative research methods. However, in spite of this popularity there is still uncertainty regarding both the approaches methodological orientation of and the

procedures undertaken (e.g. Cutliffe, 2005, McGhee, Marland, & Atkinson, 2007, Suddaby, 2006). Taking into account the differences in how the method is described, utilised and taught, it is proposed by Bryant and Charmaz that, rather than considering the Grounded Theory Method (GTM) as a distinct group of methods sharing precise common attributes, it should be thought of as a "family of methods claiming the GTM [Grounded Theory Method] mantle" which share "family resemblances or similarities" (Bryant & Charmaz, 2007, p11). The disputed nature of grounded theory has provoked requests that researchers be more explicit regarding the way they are utilising the method (Locke, 2001). Therefore, I will outline the theoretical and procedural underpinnings of the GTM and describe how the research process which I employed has been informed by these.

Grounded theory has its theoretical foundations in symbolic interactionism (Hammersley, 1989). Symbolic Interactionism is a sociological perspective derived from the work of Cooley, James, Mead, and Blumer and is acknowledged as providing a unique way of studying human behaviour and interaction (Denzin & Lincoln, 2011). Denzin and Lincoln (2011) define symbolic interactionism as a sociological theory that gives emphasis to the meaning in human behaviours and interaction. According to the symbolic interactionist perspective, "people construct selves, society, and reality through interaction" (Charmaz, 2006, p189). Symbolic Interactionism also presents a means of sociological

investigation into human interaction (Denzin & Lincoln, 2011).   In this sociological investigation, data collected from a social situation can be explored in a systematic way and a social science theory can be constructed (Denzin & Lincoln, 2011, Robrecht, 1995). The three principles of symbolic interactionism are that:

> [Firstly] human beings act towards things on the basis of the meanings that the things have for them….[secondly] the meaning of such things is derived from, or arises out of, the social interaction that one has with one's fellows….[thirdly] these meanings are handled in, and modified through, an interpretive process used by the person in dealing with the things he encounters. (Blumer, 1969, p2).

In essence, the ontological assumption of symbolic interactionism is that, through interactions between people, meaning is both constructed and changed (Hallberg, 2006). Furthermore, the meaning people ascribe to a situation influences the way they act in that situation (Hallberg, 2006).

As with other forms of qualitative research, the grounded theory methodology has evolved over time and there is now more than one approach. McCallin, (2003) identifies three versions of grounded theory; the original version, the 'Glaserian' version (after Barney Glaser) and the 'Straussian' version (after Anslem Strauss) (terms coined by Stern, 1994). Creswell (2012) also identifies three versions labeled, emergent (Glaser), systematic (Strauss & Corbin) and constructivist (Charmaz).   Denzin (2007) however, identifies seven versions, namely positivist,

postpositivist, objectivist, constructivist, situational, postmodern, and computer-assisted.

Bryant and Charmaz state that;

> Researchers need to be familiar with GTM, in all its major forms, in order to be able to understand how they might adapt it in use or revise it into new forms and variations (Bryant & Charmaz, 2007, p.17).

Therefore in line with this assertion, the main grounded theory approaches will be outlined and compared.   For the purpose of this thesis I will outline the 3 versions identified by Creswell (2012). Firstly comparing and contrasting the Glaserian and Straussian approaches then describing the Constructivist method and explaining my reasons for selecting the approach.

Glaserian and Straussian versions of grounded theory

Initially there does not seem to be much difference between the two versions.   For example, they both share several features including delaying the literature review until analysis is well under way, concurrent data collection and analysis, the constant comparative method, using an inductive approach meaning that categories and codes are constructed from the data rather than from predefined hypotheses, the development

of the theory throughout the analysis, the use of memos to develop categories and theoretical sampling for theory development, not for representativeness. However, the two versions have several important differences. One such difference is how the theorists operationalise the grounded theory method. For example the procedure they use for coding, how the literature is employed and whether they verify or generate a theory.

With regards to the coding procedure, the method advocated by Strauss and Corbin is heavily reliant on a structured coding paradigm (consisting of open, axial, and selective coding). According to Glaser (1992), this method is reverting back to the confirmatory methods that they had tried to avoid as it constrains the data through "full conceptual description" (p.3).

When looking at how the literature is employed and whether the researcher generates or verifies a theory, while both researchers acknowledge that a researcher cannot enter a field free from knowledge, they do however differ in the role they see for this previous knowledge. Corbin and Strauss (2008) assert that the researcher's existing ideas and

knowledge could legitimately influence the grounded theory and aid understanding. Glaser (1992) however, asserts that "categories emerge upon comparison and properties emerge upon more comparison. And that is all there is to it" (Glaser, 1992, cited in Charmaz, 2000 p.512). Glaser (1992) therefore asserts that the data must emerge without 'forcing' it into a pre-existing coding paradigm. In Glaser's 'purist approach' to grounded theory the researcher is described as being professionally naïve and due to this the generation of the theory is not compromised by the researchers own prejudices and pre-existing ideas (Denzin, 2007). Any reading the researcher does, Glaser argues, should be only around the general problem area and the more focussed reading should be carried out following the development of the emerging theory.

Another specific difference between the Glaserian and Straussian approaches is the role of the researcher in the research process. Strauss and Corbin (1990) stress that the researcher's role is a very active one in which they essentially cross-examine the data; Glaser on the other hand sees this as a violation of his more reserved approach in which, unlike the Straussian approach where they actively engage with the data the

researcher undertaking the Glaserian approach remains completely

distant and independent from the data being studied.

Selection of Constructivist Grounded Theory

Within the various grounded theory approaches, the Constructivist

Grounded Theory method is a principal tradition (Bryant & Charmaz,

2007). While the earlier Glaserian and Straussian formulations of the

GTM come from an objectivist, positivist direction, constructivist grounded

theory comes from a subjectivist approach (Bryant & Charmaz, 2007).

The subjective approach focuses on "how data, analysis, *and*

methodological strategies become constructed, and also takes into

account the research contexts and researchers' positions, perspectives,

priorities, and interactions" (Bryant & Charmaz, 2007, p.10). Therefore,

epistemologically, constructivism highlights the subjective

interrelationship between the researcher and participant, and emphasizes

the fact that meaning is co-constructed (Charmaz, 2006). Incorporating

an interpretive, constructivist approach into the grounded theory

methodology Charmaz defines the approach as:

> A social scientific perspective that addresses how
> realities are made. This perspective assumes that
> people, including researchers, construct the realities in
> which they participate. Constructivist inquiry starts with
> the experience and asks how members construct it. To
> the best of their ability, constructivists enter the
> phenomenon, gain multiple views of it, and locate it in
> its web of connections and constraints. Constructivists

acknowledge that their interpretation of the studied phenomenon is itself a construction. (Charmaz, 2006, p.187)

Therefore, constructivism "assumes the relativism of multiple social realities, recognises the mutual creation of knowledge by the viewer and the viewed, and aims toward interpretive understandings of subjects' meanings" (Charmaz, 2000, p510).

A review of studies employing a Constructivist Grounded Theory Methodology revealed a number of articles across varying disciplines including nursing (Mills, Francis & Bonner, 2008; Mills, 2009; Plakas, Cant & Taket, 2009), psychology (Sabiston, McDonough & Crocker, 2007) and education (Edwards & Jones, 2009).

Glaser (2002) however, is strongly opposed to the constructivist approach to grounded theory. He criticises the approach for what he describes as "descriptive capture", where the researcher rather than going beyond the abstract meaning of the data, seeks to get an accurate description of the data. Glaser argues that grounded theory is about "concepts not accurate descriptions". Bryant (2003) offers a rejoinder to Glasers' objections, arguing that there is confusion between the distinct methodological positions within various grounded theory approaches and that an appreciation of these differences needs to be reached to clarify the people's understanding. This argument is supported by Corbin

(2009) who, when discussing the various approaches to grounded theory, states that

> "though each of their contemporary and descendant methodologies is somewhat different, all have the capacity, if carried out properly, to do just what was intended: develop useful theory that is grounded in data" (Corbin, 2009, p52)

To summarise the development of the various grounded theory approaches discussed in this chapter Figure 1 below illustrates the key stages in Grounded Theory.
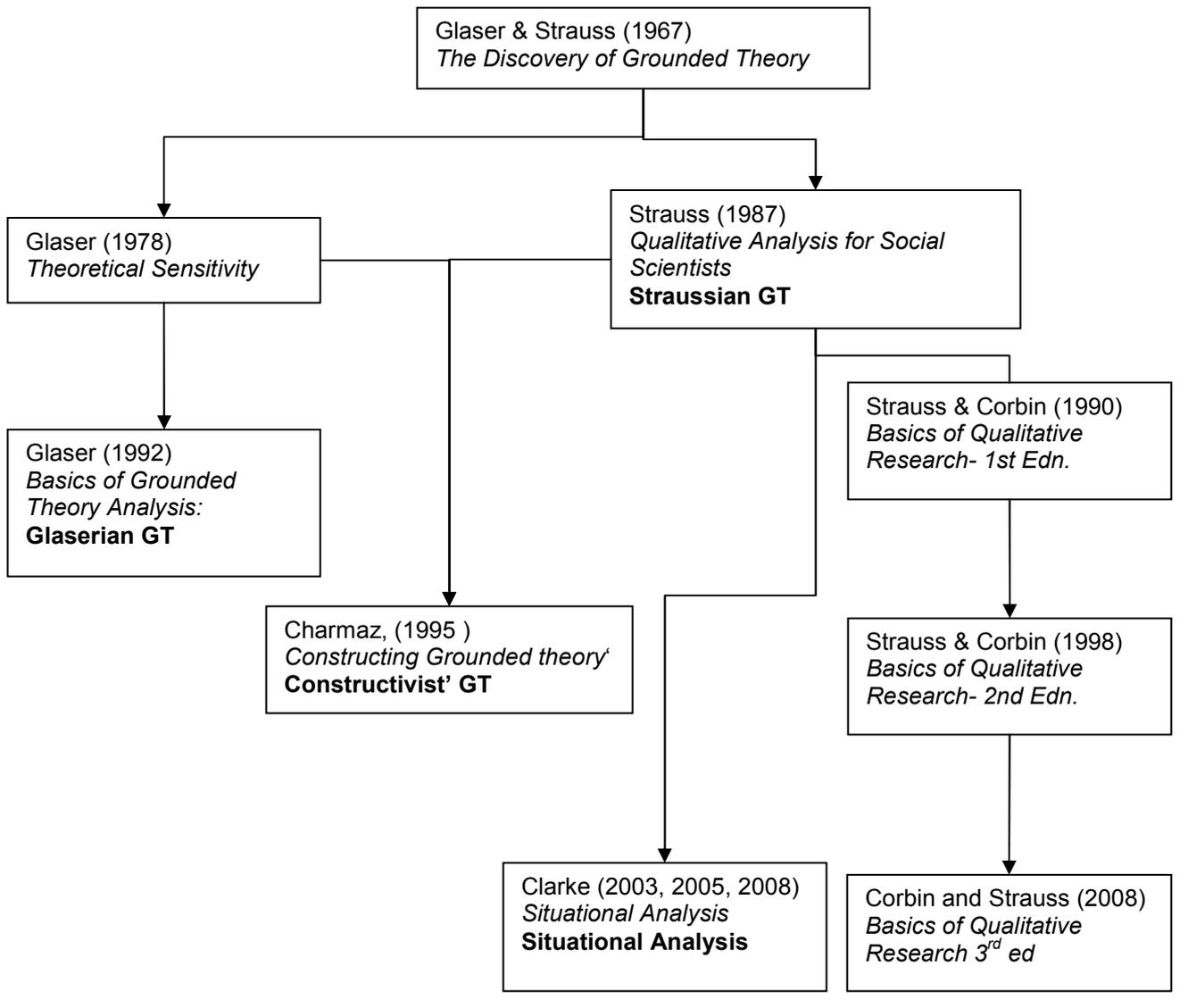
Figure 1- Grounded theory stages of development (adapted from Harwood, 2002, p67 & Morse, 2009 p17)

The constructivist grounded theory process

As I was employing a constructivist grounded theory approach, coding of data was undertaken according to the processes described by Charmaz (2006). Charmaz does not provide a detailed explanation of the stages linking the main phases of coding and analysis, preferring instead to provide flexible guidelines. The following sections outline the processes that were used in this research, starting with the two phases of coding, initial and focussed coding. I then outline the grounded theory strategies employed, such as theoretical sampling, constant comparative analysis, and memo-writing. Finally I will discuss the role of the researcher within the study.

Initial coding

Coding of the emerging data was undertaken as it was collected, by doing this I was able to start to define and categorise the data. An initial course of action in studying the emerging data involved line-by-line coding. This form of coding required examining each of the transcripts from the participant interviews, as well as their stories, line-by-line. This form of coding prompted close study of the data – line-by-line – and the beginning of the conceptualisation of ideas (Charmaz, 2006).

Focused coding

The next main step in the coding process is described by Charmaz, (2006) as focused coding. Compared to initial coding, focused coding is more selective, directed and conceptual and this coding was used to amalgamate and explain larger segments of data (Charmaz, 2006). It necessitated using the most significant or common previous codes to sort through this data (Charmaz, 2006). When undertaking focused coding, I moved across the interviews, and compared them. For example, for the code 'getting back to normal' I looked at all of the interviews to see how each person talked about how they got back to normal following the ICD implantation and this allowed me to refine the code "getting back to normal" and go on to develop "getting back to normal" as a category.

A category is defined by Charmaz (2006) as a theme or variable that aims to make sense of what the participant has said. It is interpreted in the light of the situation, and other interviews, and the emerging theory. Essentially, "categories explicate ideas, events, or processes in the data" (Charmaz 2006, p91).

At the heart of the Grounded Theory method is an iterative spiral of purposive data gathering and analysis (Bryant & Charmaz, 2007). Through this process theoretical concepts are constructed, assessed and developed from the data (Bryant & Charmaz, 2007). This is continued through progressively higher levels of theoretical abstraction. This

repetitive process alternating between the data, and the concepts being developed persists until a theory has been constructed (Charmaz, 2006). This therefore explains the variation in the data (Bryant & Charmaz, 2007).

A description how I carried out the coding process is located in Chapter 5.

The constant comparative method and theoretical sampling

The main features of qualitative analysis in the grounded theory approach are the constant comparative method and theoretical sampling (Glaser & Strauss, 1967; Glaser, 1992; Strauss, 1987). Glaser and Strauss describe the constant comparative method as being essential in developing a theory that is grounded in the data. When following the constant comparative method, sampling, data collection and data analysis are considered as a continuous sequence of data collection, analysis and sampling and not separate procedural steps in the research process. Therefore, coding and analysis occur simultaneously (Glaser and Strauss, 1967). While, the analysis and results sections are written in what appears to be a linear fashion, in defined stages, in reality the process is actually a non-linear one.

Constant comparison is said to be closely associated with theoretical sampling. During each stage of the data analysis, new data and concepts were constantly being compared with the previous data

(Charmaz, 2006). Consequently, these concepts are tested and developed in later iterations of theoretical sampling (Charmaz, 2006). This process continues throughout until the theory is developed (Charmaz, 2006).

Theoretical sampling is defined by Glaser and Strauss (1967) as:

> …the process of data collection for generating theory whereby the analyst jointly collects, codes, and analyses his data and decides what data to collect next and where to find them, in order to develop his [sic] theory as it emerges (Glaser and Strauss, 1967, p45).

According to Charmaz (2006) "Theoretical sampling involves starting with data and then examining these ideas through further empirical enquiry" (p102). It is described by Denzin (2007) as a crucial factor within grounded theory and relies on the comparative methods of grounded theory.

Grounded theory employs non-probability sampling where participant numbers are not known prior to the start of the study (Cutcliffe 2000; Glaser & Strauss 1967; Strauss & Corbin 1990, 1998). Conforming to Glaser and Strauss' (1967) and Strauss and Corbin's (1990, 1998) instructions, the sampling is theoretical, rather than purposive or initial. Theoretical sampling differs from purposive sampling and initial sampling in several ways. In initial sampling, criteria for people, cases or situations are established prior to entering the field. Purposeful sampling seeks a

representative sample based on, for example, quotas or demographics. Conversely, theoretical sampling relates to conceptual and theoretical development – based on the theoretical analysis the researcher is directed as to where to go to sample the next interviewee (Charmaz, 2006). In theoretical sampling; statements, events or cases are sought to illuminate categories so as to fill the properties of the categories, as well as to assist in determining how processes develop and change. However, while it is a key component of grounded theory, there is little guidance available regarding how to carry out this process. Initially purposive sampling was undertaken to recruit the first few participants, analysis of the data from those interviewed informed future data collection. Theoretical memos helped me to explore and refine the data collection strategy; this is more fully explained on page 79. Theoretical sampling required me to check my ideas against direct empirical realities, moving back and forth between the category and the data (Charmaz 2006, p110).

The analytic process of constant comparison, central to grounded theory was employed at all stages of the research. The interview material was analysed and coded as soon as it was collected, to identify theoretical elements from which theoretical concepts were developed.

Theoretical saturation

In grounded theory, data collection stops and the development of the theory takes place when saturation occurs. Charmaz (2006) states that saturation is reached when no new categories or properties emerge from obtaining additional new data. In the GTM, researchers aim for analytic generalisability (where it can conceivably account for a large number and range of empirical observations) rather than the statistical generalisation that quantitative, positivist researchers aim for. This is the reason why grounded theorists utilise theoretical sampling instead of, for example, randomised participant selection within a statistically representative population.

Memo writing

Research memos are defined as "the theorizing write-up of ideas about codes and their relationships as they strike the analyst while coding" (Glaser, 1978, p.83). Alongside the constant comparative method of data analysis and in keeping with the GTM, I wrote memos throughout the research. These memos represented my ideas, feelings and my interpretation of the data during the analysis. They were referred to throughout the interview process and subsequently used to assist in the development of the model. Charmaz, (2006) proposed that memos were the pivotal intermediate stage between data collection and theory generation. I wrote memos following each participant interview. An

excerpt of the memo I wrote following my interview with Participant K is in

Figure 2, below

> This was quite an eye opening interview for me in relation to how the participant and his wife coped with the ICD. They both were very open and matter-of-fact about the whole experience.
>
> What struck me most about participant K and his wife was how they found the humour in the situation. For example he joked about how the doctors had to save his life before they told him he needed to have an ICD, they made jokes about how the ICD hasn't affected his social life, as he never had a social life in the first place, and how their grandchildren threaten him with a magnet.   I didn't realise that magnets affect the functioning of the ICD. Although they used humour a lot in the interview. It didn't seem inappropriate, and it seemed to me to be their way of coping with the situation.   Thinking about the other participants I had interviewed many of them had made some jokes and used humour in some way, however Participant K, his wife and family seemed to use humour more than others. However the humour seemed to be in a supportive way and a way of demonstrating that they were coping with the situation. I will follow up on this is my next interviews, and see if other participants use humour in this way.
>
> What was also surprising to me was that he had experienced multiple shocks, quite a few in a row one after the other, and described these shocks as feeling like a horse kicking him in the back, but he was still glad he had the ICD implanted and overall it had had a positive impact on his life. However, reflecting on this I realise that while to me the thought of having a machine implanted that could deliver a painful shock without any warning seems to me to be a scary thing to happen, I have never experienced tachycardia and I have never been close to death, and told that if I don't get an ICD I could die, so I can't say conducively that I would not see the ICD as I positive thing after it had shocked me.
>
> As a couple they seem to me to have a really strong relationship. They are sitting closely together on the couch and when they answer one of my questions they look to each other to confirm their responses. Possibly the strong relationship they have also helps them to cope with the ICD.

Figure 2: Excerpt from memo written following the interview with

Participant K.

I also wrote memos regarding the codes I was developing, According to Charmaz (2006) these conceptual memos are used to record thoughts regarding what the codes mean, describe the processes occurred, how the processes changed, and the consequences of these changes. In these memos, compared the interview data, with the codes I had identified in order to find similarities and differences. I highlighted any questions that I felt should be asked in subsequent interviews in order to further explore concepts that had been identified. For example, initially the category living with uncertainty was called dealing with uncertainty, however following examination of both the memos and the focused codes I identified that the participants were not talking about how they dealt with the uncertainty but how they lived with the uncertainty. Figure 3, below provides excerpt of one of the conceptual memos I wrote when developing the category, living with uncertainty.

Living with Uncertainty

Participants, when talking about their experiences of living with the ICD talk about the unpredictability of living with the device and the fact it could shock them at any moment, without warning. When describing this, they use words like afraid, anxious, unexpected, and say things like they are "not sure of the future" and how "it literally shocks you". They talk about how the shock is something that they can't control and how they have to cope with the unpredictability of living with the ICD. The fear of the shock is something that both those who have had a shock and those who have not had a shock talk about and this often leads to anxiety for them.

While initially I named the category dealing with uncertainty, participants don't specifically focus on the things they do to cope with and alleviate the uncertainty; rather they talk about how they live with the uncertainty and incorporate it into their lives.

Figure 3: Excerpt from a conceptual memo.

Constructivist grounded theory differs from traditional or classical grounded theory that considers the participant's reality is discovered by the researcher and that theory emerges from the data quite separate from the researcher. Rather, constructivist grounded theories are created through the researcher's "past and present involvements and interactions with people perspectives, and research practices" (Charmaz 2006, p10) and what the researcher brings to the data influences what they see within it (Charmaz 2006, p15). Therefore, following the constructivist grounded theory methodology; it was assumed that reality was created by both the participants and myself as researcher.

Reflexivity: The role of the researcher

In qualitative research, the researcher is the instrument for data collection and analysis and therefore the role of the researcher is an integral component (Strauss and Corbin, 1997; 1998). As noted by Boss, Dahl and Kaplan (1996) the role and knowledge of the researcher needs to be recognized. This assertion is supported by Hill et al. (2005) who highlighted that during interviews there are several possible sources of researcher bias. The main sources of potential bias they identify are the demographics of the researcher, their theoretical background and the values and beliefs the researcher holds about the topic.

Yardley (2007) asserts that this influence is inevitable and by attempting to eliminate this, the benefits of qualitative research, for example the

disclosure of subjective experiences in an in-depth interview may not be retained. Yardley maintains that by allowing the participants to influence the topic and the data, while also recognising and exploring how the researcher may have influenced the findings of the research these benefits can be maximised. Therefore as part of the data collection and analysis, I reflected on how my personal knowledge and experience would shape my inquiry and analysis of the information shared in this study.

When I interviewed the participants in this study, I was over 20 years younger than them. This, I feel could have influenced how the participants related to me. However, at the time of interviewing the participants I was working at the Centre for the Older Persons Agenda and had experience of working with older people. In addition my background in the caring profession as a care assistant in a number of care homes and my work as a behavioural therapy assistant meant that I had experience working with people and dealing with sensitive issues. I therefore felt comfortable interviewing and interacting with the participants and felt that this combined with the fact that I interviewed the participants in an environment that they felt comfortable in meant that they were at ease during the interview.

I was interviewing people who had had an ICD inserted and their partners. I had not had an ICD inserted, nor do I have any cardiac

disorder. Prior to the interviews I reflected on this and how this might impact on the relationship I built with the interviewees. However, while I did not have any firsthand experience of cardiac disorders, I had knowledge of various cardiac problems, including heart failure and ICDs through working on the self management manual for patients with heart failure. While writing this manual I learned about a number of cardiac diseases and also ICDs and was therefore able to understand what the participants were talking about when they spoke about the reasons for their ICD insertion. Furthermore, I also attended the support group's Christmas lunch which meant that I was able to meet the participants prior to the interview.

Conclusion

The ontological and epistemological underpinnings of this research are fitting with the aims, design and the research methods of this study. Employing a qualitative approach meant that the focus is on understanding rather than predicting and meanings, processes and context are emphasised. Constructivist grounded theory, underpinned by symbolic interactionism, directed the study and procedures employed. A symbolic interactionist perspective assumes that society, reality and self are constructed through interaction and that interaction is inherently dynamic and interpretive (Charmaz 2006). In constructivist grounded theory, the researcher is part of the world of study and the theoretical

depictions are an "*interpretive* portrayal of the studied world, not an exact picture of it" (Charmaz 2006, p10). Understandings are created from shared experiences with participants and will therefore allow for the generation of a model or theory within a relatively unknown topic (Pidgeon & Henwood, 1996).

The following chapter focuses on the research methods used based on the purpose of the study.

Chapter 5

Data Collection

In the following chapter I will present and justify the data collection method I employed in this study. To do this both the strengths and suitability of the semi structured interview approach for this study will be discussed. Moreover, the selection and recruitment of the participants will be described and the method of data collection will be outlined.

Method of data collection

As mentioned in previous chapters a qualitative research method is being utilised in this study. As Charmaz states:

> Qualitative researchers have one great advantage over our quantitative colleagues. We can add new pieces to the research puzzle or conjure entire new puzzles – while we gather data - and that can even occur late in the analysis. The flexibility of qualitative research permits you to follow leads that emerge. (Charmaz, 2006, p14)

There are several qualitative methods of data collection available including interviews, focus groups, questionnaires, documentatory analysis and observation. While Silverman (2009) asserts that there is no right or wrong method, he does emphasise that there are methods that are more appropriate for each particular research topic and methodology

employed. Lewis (2003) purports that the researcher needs to first consider which approach to employ.

The qualitative data collection method employed in this study is semi-structured, in-depth, face-to-face interviews. Interviews are deemed by Charmaz (2006) as the most appropriate and commonly used method of data collection in grounded theory research. Bulmer (1969) cited in Seidman (2010) states that in in-depth interviewing, the meaning people construct from their experiences influences how that experience is performed. This is in keeping with the idea of symbolic interactionism described in Chapter 4.

To provide a framework for the interview, a semi structured interview schedule was developed. This schedule was used as a guide, but actual interview questions came from the participant's statements and responses as the interviews progressed (Rubin & Rubin, 2005). This meant that I was able to gather additional data to support and confirm my findings. The interview is probably the most widely employed method in qualitative research (Silverman, 2011). In qualitative interviewing the interviewer can diverge from the schedule, ask further questions that expand upon interviewees replies and vary the order and the wording of questions (Rubin & Rubin, 2005). Following the method of grounded theory, the interview schedule was reviewed after each interview and questions adapted where necessary (Charmaz, 2006). Open-ended

questions were used to guide, but not lead, the interview. Patients and their partners were encouraged to speak freely about the questions and raise any issues and concerns that they had to ensure that all of the concerns and educational needs of patients and partners emerged during the interview.

Selection of participants

To be eligible to participate, potential participants needed to either have had their first ICD inserted in the past three months-five years or be the partner of someone who had. I had decided to interview partners as well as the patients as, even though partners were identified as being a main source of support for patients, I had identified a dearth of knowledge regarding the experiences of partners. Sampling came to an end when I determined that theoretical saturation of each category was achieved. Creswell (2002) asserts that saturation is "the state in which the researcher makes the subjective determination that new data will not provide any new information or insights for the developing categories" (Creswell, 2002, p.450). However, Josselson and Lieblich (2003) emphasise that individuals have unique narratives or stories and therefore the kinds of categories presumed to be inclusive of all experiences are infinite. Nevertheless, Corbin and Strauss (2008) assert that theoretical saturation may be reached when no new themes,

categories or relationships seem to be emerging and any new data gathered confirms the findings from the previous data.

Method of recruitment

The participants in the present study comprised of a convenience sample. Male and female patients with ICDs were recruited though a 'call for participants' message in a support group's newsletter (see appendix 2) and from the support groups 'festive lunch' where I spoke in person to the attendees, outlining the study, inclusion criteria and what participation involves. I also employed "snowball sampling" and requested that participants consider recommending other possible eligible participants. All participants were provided with my contact details, including my work telephone number and e-mail address.

Support group description

The support group identified was a patient led support group with charitable status. As it is the only support group specifically for ICD recipients in Scotland, the group draws members from the only two cardiology centres that implant defibrillators in Scotland. Therefore support group members come from all over Scotland. Due to geography, only one annual meeting is held, with regional groups meeting 2-3 times a year. Contact with group members is through a newsletter published 4 times a year. Other services include information leaflets regarding living

with the ICD. A befriending service and hospital visits to meet new ICD patients.

Ethical Issues

The research proposal was submitted to the ethics panel at Queen Margaret University in March 2006 (see appendix 3) and ethical approval was granted in April 2006 (see appendix 4 for the approval document). Throughout the research, I followed the British Psychological Society (BPS) Guidelines for Ethical Research and Code of Conduct (BPS, 2006, updated 2009),

I am aware that studies conducted with people with a chronic illness and the relatives and carers of people with chronic illness must be conducted sensitively and, following the BPS (2006) guidelines, several steps were therefore taken to ensure the study was conducted ethically:

- The participants were given time to ask questions about the study, to ensure that they understood fully about the research and what participating involved.
- Informed consent was obtained and confidentiality was assured.
- Participants were informed that participation in the study was voluntary and they were assured that they were free to withdraw at any time without giving a reason.

- Prior to the interview the participants were informed that they did not have to answer any questions that they did not want to answer.

- The questions asked in the interview were ones that are routinely asked in hospital and similar research and it was not envisaged that any of the participants would become upset. However, if they had become upset the researcher would have stopped the interview and referred the participant to either the support group or their general practitioner for further help.

Informed consent

Each participant received an information sheet (see appendix 5), which included;

- Contact details for both the researcher and supervisor,

- Contact details for another researcher/academic at Queen Margaret University who had knowledge of the study but was not involved in the study, should the participants wish to speak to someone who is impartial,

- The purpose and aims of the study,

- A description of the research process,

- An outline of what the participants will have to do and the amount of time involved,

- A statement about the voluntary nature of participants involvement,

- A statement regarding the confidential nature of the study, and how anonymity will be maintained.

Informed consent was reviewed prior to the interview commencing and each participant was given the opportunity to ask questions and clarify any issues. A consent form (see appendix 6), which was separate from the information sheet, was also included that reinforced the information given to the participants regarding the voluntary nature of the study, the fact that the participants were given time to ask questions, and the fact that they were able to stop the interview at any time without having to give a reason to the interviewer. Furthermore, as recommended by Miller and Bell (2002), consent was an ongoing process and was reviewed and/or renegotiated in collaboration with participants.

Research interview process

All interviews were conducted in private and at a time and location that was both convenient and comfortable for them. In all but one interview, this location was at their own house. In the other interview, this location was the house of their partner.

Each interview began with the open-ended question "can you tell me a bit about the circumstances surrounding the ICD insertion?" This question allowed the researcher to introduce the topic and then guide the interview from the responses given to that first question. A copy of the interview schedule that guided the interview is located in appendix 7, the supplementary questions that were included in the interviews where I also

interviewed the partners/carers is located in appendix 8. As theoretical sampling techniques were employed, the open ended questions became more focussed as time went on. This was in accordance with the findings of the previous interviews that had been carried out and also the use of the constant comparative method in the analysis of the data.

In addition, demographic data were collected from each participant (in the form of a pre-interview questionnaire). For the patient with the ICD the information obtained was age, gender, occupational status, marital status and, if married, for how long, reason for ICD insertion, when the ICD was inserted and how many times the ICD had 'fired' (see appendix 9). For the partner the information included relationship to partner, age, and gender (see appendix 10).

Data Management

The interviews were audio recorded and transcribed verbatim soon after the interviews were conducted. Audio recording of the interviews meant that a complete record of the interview for data analysis was obtained and I was able to concentrate on the interviewees responses and interact with the interviewee. Key word memos were also written during the interview to assist with the analysis. Comprehensive notes were also made following each interview to support the data analysis. Each tape was listened to in full before transcription, again whilst transcribing the

contents and finally replayed again whilst reading through the interview transcript. Although it was time consuming (it took between four and six hours to transcribe each interview) I transcribed the interviews myself. By doing this, I was able to become immersed within the data and therefore closer to the lived content of the interview. This meant that when I later re-read the words, the mispronunciations, inflections or emphases, remained with me – I heard their voices, and this was a way of coming as close to them as possible through the data. The process of transcribing also required a degree of sensitivity to the process of transforming oral language to written text representation.

During the transcription, a code was used to replace any first or family names mentioned in the interviews. Unlike other research methods, the grounded theory method does not require respondent validation of the interview transcripts. The nature of the constant comparative analysis and theoretical sampling infers that the researcher expands the scope of their sampling involve other people who have had different experiences to ascertain whether the theory they are developing holds as new data is collected (Elliott & Lazenbatt, 2005).

Coding the data

When initially coding the data often the participants own words (in vivo coding) or gerunds (words ending in 'ing' that reflect process rather than topic) were used as codes. This was in order to convey a sense of action

and imagery as well as to stay close to the data, and therefore the meanings the participants were conveying. Starting with the words and actions of the participants helped to preserve the fluidity and provided a way of looking at their experience, from their perspective. While initially I did not use Computer-Assisted Qualitative Data Analysis Software (CAQDAS), following my initial coding as I was attempting to carry out more focused coding; I realized that, as someone with limited experience carrying out qualitative data analysis, managing over 2000 initial codes was proving both challenging and complicated. I was also nervous that I would start 'forcing' the data into emerging categories and also potentially lose some relevant codes. Therefore I decided to transfer all of my data into the CAQDAS package, NVivo. While this took some time to transfer all of the initial codes and the focused codes I had identified so far into NVivo, it helped me to organise, rearrange and manage the date more effectively.   I was also able compare and combine initial codes more easily.

Increasingly software programmes are being used to assist in the process of data analysis through facilitating theoretical sampling and "constant comparison" across cases (Seale 2005).   Through 'constant comparison' all main categories and underpinning focus codes, from my study led to the development of a core category. All main categories and codes were compared and memos were sorted to identify how they all related to each other to enable the development of a grounded theory model. The core

category is a distinctive category that sits at the heart of the developed grounded theory model and summarizes what is happening. All other major categories should relate to the core category, which ought to appear frequently in the data (Strauss and Corbin, 1998). See appendix 11 for some examples of how the interview transcripts were coded.

Conclusion

This chapter comprised a description of and rationale for the data collection process employed in this study. Also included were the recruitment and selection process and the data management procedures of the study as well as a description of ethical considerations applied in this research. The following chapter will present the results of the grounded theory study.

Chapter 6

Findings

The previous chapters have provided an introduction and background to the study and both justified and described the research design and methods used to carry out the research. The following chapter will present the results of the analysis and the subsequent grounded theory model developed. I present my analysis from the perspective of the experiences and views of the patients and partners who participated in the interviews.

The participants' acceptance of the ICD is influenced by how they got back to normal following the ICD implantation. This process is influenced by how informed they feel regarding living with the ICD. Conversely, the information they require is influenced by how the ICD impacted on them getting back to normal. The analysis was conducted in a systematic but non-linear fashion using the constant comparative technique outlined in chapter 4.

Participant characteristics

During the course of the data collection, 14 participants were interviewed, nine males and five females. The participants were aged between 48 and 75 years. Four had their ICD's inserted for primary prevention, 11 for

secondary prevention. Table 2 below, provides an overview of the aggregated participant characteristics, appendix 12 provides a full description of each participant and the codes allocated to each participant (participant A – Participant N). Where the responses were from the partner of the ICD patient, the code given was the code allocated to the corresponding patient followed by the number 2, for example the partner of participant A was A2.   I was only able to recruit four partners, and to try to address this problem of non participation I asked the question in the interview, how has your partner coped with your ICD, and also asked if their partner had had any question for the medical staff regarding the ICD.

As I had no access to their patient records I could not determine the exact medical reason for their ICD implantation, I only had the reason they told me,

The participants were interviewed between December 2007 and April 2008. The interviews varied in length from forty five minutes to one and a half hours with a mean interview time of fifty five minutes.

Table 2: Aggregated Participant Characteristics.

	Male (n=9)	Female (n=5)	All
Age (range, mean)	49-75 (64.1)	48-57 (53.6)	(48-75) 60
Marital Status	7 Married, 2 Living with Partner.	5 Married.	12 Married, 2 Living with Partner.
Occupational Status	7 Retired, 2 Employed.	1 Retired, 2 Employed, 1 Unemployed.	8 Retired, 4 Employed, 1 Unemployed.
Primary or secondary prevention	2 Primary, 7 Secondary.	2 Primary, 3 Secondary.	4 Primary, 10 Secondary

The Grounded Theory Model

A diagrammatic representation of the grounded theory model that emerged from the data is depicted in Figure 4. The format of this chapter and the explanations provided will be based on the grounded theory model. The core category Accepting the ICD described how the recipients came to reconstruct their life following the implantation of the ICD. This chapter will focus on the core category, Accepting the ICD and the two subcategories – (1) getting back to normal and (2) feeling informed.
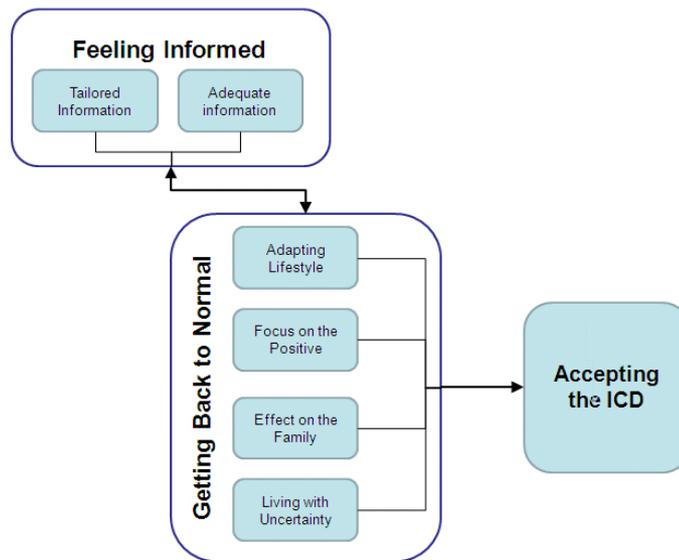
Figure 4: Grounded theory Model: How the experience of living with an ICD influenced patients and their partners educational needs and concerns.

Getting Back to Normal

Getting back to normal emerged as a category in response to the participants descriptions of what their life was like following the ICD implantation. This was experienced in 4 ways (1) adapting their lifestyle, (2) focusing on the positive, (3) dealing with the effect on their family and (4) living with uncertainty. This category was focussed on by the majority of patients. Figure 5 provides a descriptive illustration of the category and subcategories. Each participant spoke about all four of the categories, however they experienced them in different amounts.
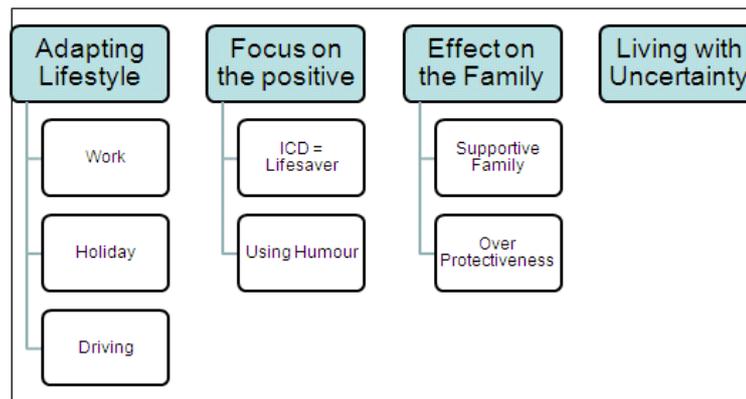
Figure 5: Descriptive model of the Category Getting Back to Normal

Adapting lifestyle

Adapting their lifestyle emerged as a way for the participants to get back to normal. Over time the majority of the participants adapted to the life changes and returned to normal activities:

> I still go out I go out for a night and go to the dancing eh and I do everything that I did before, everything I did before, so I am happy. (Participant G)

> I like to go walking, and that, I don't jog or anything like that, I am not a fisherman or a golfer, or any of these things, so I still go walking and things like that when I can, such as it is round this area. (Participant A)

> No, I am no allowing it to change. No it hasne [has not] changed at all quite fine. [pause] Aye I still go out I go out for a night and go to the dancing eh and I do everything that I did before, everything I did before so I am happy. (Participant G)

However others found that they were not able to engage in as much physical activity as they used to as they now get too tired:

> I get too tired, so when it comes to that then yes I mean it affects me (Participant D)

When talking about how they adapted their lifestyle following their ICD, participants identified four main areas: work, holidays and driving. The properties and dimensions of the category Adapting Lifestyle are now discussed. An illustration of this category is provided in Figure 6 below.

```
          ┌─────────────┐
          │  Adapting   │
          │  Lifestyle  │
          └──────┬──────┘
      ┌──────────┼──────────┐
 ┌────┴────┐ ┌───┴────┐ ┌───┴─────┐
 │  Work   │ │Holiday │ │ Driving │
 └─────────┘ └────────┘ └─────────┘
```
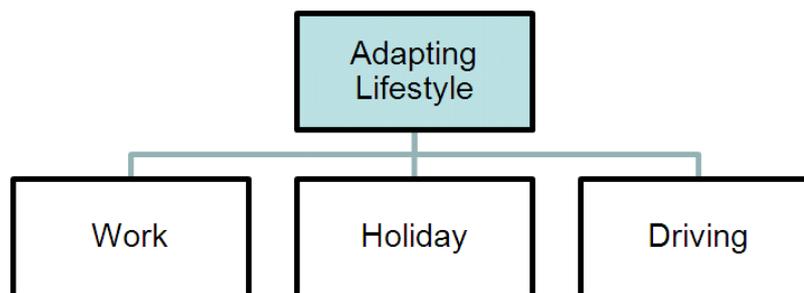
Figure 6: Adapting Lifestyle

Work

While the majority of the participants had retired, a few participants were still employed and spoke about how the ICD had impacted on their working life. One participant was in military service and spoke about how he was unable to go back into active duty, and how his role in the military would change:

> I think my overriding concern was what's the [military's] view going to to take of this, what's my job ehm going to be ehm, I will not be going to the front line so I'll not be going to [conflict region] [laughs] in three weeks and then there is the question over what do I do as that had been part of my job. (Participant A)

Another participant had to retire due to being unable to do his job:

> "I was a bus driver and I cannae drive my bus anymore, [laughs] so I'm retired now" (Participant F)

One of the younger participants, who did return to work, spoke about how her ICD impacted on how her colleagues reacted around her:

> if I am in work, if I even go ouch they go 'are you OK, are you OK' and I am like that don't panic. Only panic if I faint. I'm fine [laughs]. So it does have an effect on them. They tend to sort of. I don't know, they tend to be less confident than I am, sort of style. I've told them what to expect, if anything happens, what they've got to do, I've made sure they've got wee copies of the leaflets, so that they can read it, and I've asked them if they have any questions to ask me. I've given them the website to go on and read about it. (Participant M)

One participant spoke about her experiences with the occupational health department when she returned to work, where she felt that the occupational health nurse should have taken the time to learn about her ICD and how she felt about the fact that the nurse hadn't taken the time to get any information on the ICD.

> The nurse at work you know the, occupational health, when I went back to work I had to make them aware that I have got this, she knew absolutely nothing about it. She had to ask me where she could find information, and I felt totally insulted by that, I just looked at her and I said to her, are you telling me, are you telling me, in [company], that I'm the only person that has an ICD, I says because I find that very difficult to believe, and the fact, I says, that I am working on their behalf, and you haven't even, as far as I'm concerned, taken the time to look this up doesn't give me a lot of confidence, I got very angry (Participant E)

Holidays

Several participants spoke about how the ICD had affected holiday plans

and how having the ICD affected where they could go on holiday.   For

example, having to go to destinations that had hospital facilities nearby

that had provision for someone with an ICD:

> I lost a holiday through this; I lost my deposit as well.   I was
> booked to go to China, in March last year, because of this,
> well I hadn't got a licence for a start, because of this I was told
> that China didn't have the necessary equipment to reset this,
> yet. (Participant L)

However, while this was said to impact on their holiday destination, for

many participants, it did not impact on them actually going on holiday; it

just meant that they had to identify the destinations that had the facilities

to reset the defibrillator:

> K: I've got…the machine I've got is a [name of ICD device]
> and I went on their website, wherever you are going you can
> plug in and they will give you a list of any hospitals and clinics
> K2: Hospitals that can cater for…
> K: Clinics that can deal with, you know their defibs , and you
> know we are off to Sydney in 2 months time, and then
> Auckland to see my other son and so you know I always print
> out a list, (Participant K)

Others spoke about how getting travel insurance was more difficult

and the premiums were now higher:

> When I say to him [husband] this [travel insurance] is going to
> cost an arm and a leg, because I've got this. (Participant B)

I had to pay a bit of an excess premium on my travel insurance and this sort of thing because of my condition (Participant G)

Driving

Driving was mentioned by a number of patients as a main activity that the ICD impacted on as, for many participants, being unable to drive meant having to make a number of major changes to their lifestyle:

> loss of ehm pre-attack activity that I used to do, the driving which is a pain in the backside, my last attack or my last episode was two weeks ago, so, I guess it will be another six months of that sort. It will be about another year actually living out here, not being able to drive; with no public transport is a complete and utter pain. So you have to work out ways of either having massive arguments with your wife [laughs] can you drive me here or there, you have to just do things do things a bit differently (Participant D)

> You know, so no, things like my shopping, because my husband doesn't drive, saw we just and me you know I'm the driver in the family so the driving was a huge concern but I understand why that is put in place. (Participant E)

One participant had not actually realised that the ICD meant that she would be unable to drive for 6 months until her doctor told her after she had the ICD implanted:

> He told me about my driving that I wasn't allowed to drive for six months, which, again, I knew nothing about until I was actually leaving the hospital. (Participant C)

Participant M spoke about how the ICD affected her actual driving behaviour and where she drove.

> M: I don't drive on motorways any more
> Interviewer: and why is that?
> M: I am very frightened of causing an accident
> Interviewer: right
> M: I have never been the world's boldest driver anyway, I drive to get somewhere, I would never go for a drive for fun, ehm and I am nervous driving my grandchildren I would prefer not to, and I don't drive on motorways the idea of having a shock when I am driving at speed. (Participant M)

Focus on the positive

When talking about living with their ICD all of the participants spoke about the positive impact of the ICD on their life and how they were glad they got the ICD. Two main categories emerged, the ICD being a lifesaver and also how they used humour to cope. The properties and dimensions of the category, Focus on the positive, are now discussed. Figure 7, below, provides an illustration of this category.
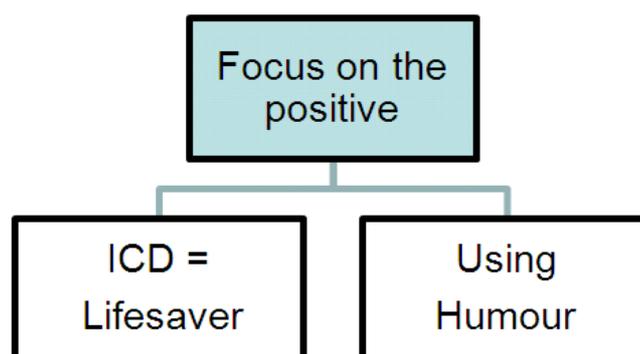
Figure 7: Focus on the positive.

ICD is a lifesaver

A shock reminded the recipients of their own mortality, but it also reassured the participants that the device was functioning properly. This is illustrated in the following extract, where Participant J is talking about how people experience a shock:

> People tend to look at this in two ways, the worst thing that has ever happened in their lives, that the, that the episode is not a one off episode, it is being repeated, eh and the second way is to say, well actually, this thing is saving your life, […] But the moment it doesn't work, you are in difficulty. (Participant D)

The majority of participants spoke about a feeling of security and described the ICD as a "safety net", a "back-up" and a "lifesaver"

> It is a lifesaver, it's a lifesaver ehm, I would have no hesitation in recommending it, [...] I would tell them that eh how helpful it has been to me and my experiences and also how helpful it has been to people I have spoken to, and other experiences ehm, and I'd say if they require it go for it big time. (Participant F)

Using Humour

Several of the participants spoke about how they and their family coped with the ICD through using humour:

> You have to find amusing things in it otherwise it just, it can get terribly depressing when you think, oh I can't do this, you know, I'll never do that again, (Participant I)

For example one participant laughed about the scar he got:

You don't get a bad scar, you get a nice scar, [laughs] you really do, some of the other scars have like jaggy bits, as if he's opened you with a tin opener. (Participant N)

A partner of one of the ICD recipients spoke about how their family used humour to cope with the ICD.

It is really only our daughter and grandchildren and the niece, but no it hasnae really [affected the family] they just threaten him with a magnet [laughs] (Participant K2)

Effect on the Family

When talking about how the ICD affects their family, two contrasting categories emerged namely the family being supportive and the family being over protective. Figure 8, below, provides a visual representation of the category.
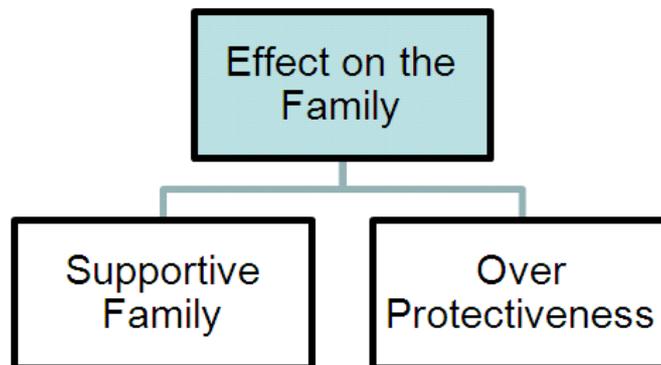
Figure 8: Effect on the Family

Supportive Family

When expressing how the ICD has impacted on family life, the participants all expressed how having a supportive family is important when coming to terms with the ICD.

> I think you have got to come to terms with yourself, in as much as I think you need to have a supportive partner (Participant N)

On participant spoke about his wife and the support he has had from her:

> She has been wonderful to me, through all my heart problems, understanding, caring, my life has not changed in that way, she is even more understanding, and more caring, I could not have been married to a nicer lady (Participant K)

Over Protectiveness

A number of the participants expressed that their partner or other members of the family were initially overprotective of them. One participant spoke about how, following him experiencing a shock his wife and his mother initially wanted to curtail the amount of activities he was doing:

> P**:** I think you [his wife] both you and my mother were more protective
> P2: yeah
> P: Than I necessarily wanted at a time when I was trying to say stop wrapping me up with kid gloves. You know, for example ehm times when I had, well the last attack I had, I was on the golf course and ehm my mother's immediate reaction was "oh well, don't play golf then, you can't be playing go" but, of

course, my response was completely different. I said that I need to play golf the next day. (Participant J)

One participant spoke about how her family were very protective and how her mother 'exaggerated' the severity of her operation.

They are very protective, perhaps too protective my mother told everybody, fortunately she lives in London, but told everybody loudly, that I had this very serious heart operation and of course everyone thought I had had open heart surgery. (Participant M)

Another spoke about how initially her husband was over protective but is now less so:

Initially he was overprotective, the first time I went abroad without him he told the guy I was travelling with that I was not to lift a bag and you know these were the only conditions I was going but all that has settled a bit (Participant B)

This reduction in over protectiveness was also experienced by Participant D whose wife spoke about her earlier protectiveness with him:

I think I have been eh slightly protective earlier on, but now, I think now you've got to, you've got to go, like you said it happens, where it happens (Participant D2)

Living with uncertainty

Living with uncertainty was another category that the participants focussed on during the interview. This main category focuses on the experience of the ICD shock and how the participant adapted to living

with the unpredictable nature of the ICD and the anxiety around experiencing a shock:

> I must admit I do get more anxious, ehm sometimes, I can worry about it and sometimes I can scare myself to pieces *(*Participant E)

Some also spoke about how this anxiety manifests itself physically and behaviourally:

> I think that this thing will think that my hearts racing kind of thing, I would say that aye [yes] I have a bit more, a bit more anxiety, I would say, definitely. I can also be a wee bit more irritable as well, you know and a wee bit quicker to anger than I used to be. (Participant A)

Many participants described the uncertainty around if and when they were going to experience a shock:

> Obviously my main concern was when am I going to feel this thing shock again and I did say to him you know when is it when is it going to shock, when is it going to go off and he just looked at me and he said hopefully never so, touch wood, it hasn't ever gone off. (Participant E)

This uncertainty led to participants experiencing anxiety:

> I think that any situation that comes up now, no matter how trivial it might appear, I am making it out a bit more than it is, because, obviously we all have wee stress levels, and the heart beat will probably rise a wee bit, but I am now I think, [..], that if I get myself into just the slightest wee bit of anxiousness, that it's going to find that fast rhythm again and just go for it and that's going to kick again and you know, it's put me on edge I have to say. (Participant H)

Whether or not they had experienced a shock, the actual fear that they

might, at some time experience the shock, was evident in a number of

participants:

> Well I do get apprehensive I think, just wondering if it is going
> to go off or, but it has never went off. (Participant L)

> I do have this underlying, fear that it just could shock me at
> any moment. (Participant C)

The experience of having a shock was described by participants as

being 'not pleasant' and frightening. This fear was described by a

number of participants, with one describing the experience of not

being in control and the fear of this:

> I: I mean it hits you and it leaves you shocked, there is nothing you
> can do
> Interviewer: so after the shock, how long are you affected?
> I: ages, I am its fear (Participant I)

Several also reported how they felt anxious and afraid about it happening

again,

> Fear, of another shock happening, well that's always there,

> (3.0) always there, but it does happen (Participant D)

One participant reporting how they lay awake at night thinking about it:

> You could be lying there or you're sitting there waiting for the next

one and your heart goes bumping away 20 to the dozen (Participant A)

Some participants described being hit multiple times in a row (known as an ICD storm), and how painful and unexpected this was:

I got hit, I thought some horse had kicked me in the back, that was really wicked I didnae [didn't] expect that, cause I was just out a month, it got fitted in November and that was, December beginning of December I got hit, and then on the 22nd of December I got hit ten times in a row. (Participant K)

Feeling Informed

The category, feeling informed, emerged from the participants talking about the information they received prior to and after the ICD was implanted and also what they would have liked to have been told. Figure 9, below provides a visual representation of the category and sub-categories.
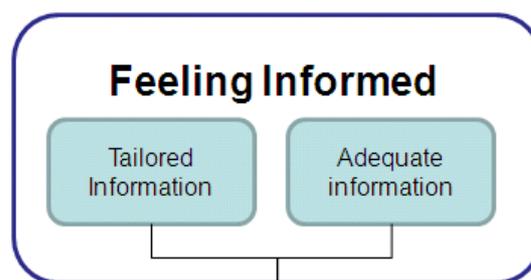
Figure 9: Feeling Informed

Participants expressed a need to feel informed about the ICD and the impact it will have on their lives. Participants were very specific about

what they wanted to know and generally wanted to know why it was happening, and what to expect after it was implanted.

> I like to know the reasons why it has been done, don't be kind to me, tell me I'd rather deal with it straight, and that way if I have got concerns I can come back to you and let you know, I would have liked to have known more about the procedure before you go in I think that they could have been, maybe more of a leaflet that could tell you exactly what's going to happen, […] obviously they can't give you every bit of advice, but ehm, maybe what to expect once you come out, ehm, I knew I was going to be and a bit of pain from it, I had to find out things like not to hold hair dryers too near, not to do that I had to find out all of these things for myself, and I would have liked to have been able to find that out. (Participant I)

Adequate information

For several of the participants, the health professionals they spoke to seemed to be of the opinion that, now the ICD is inserted and working, there is no need for any further support. Participants were disappointed with the information they were given before the ICD was inserted and the after care that they received. They felt that their concerns had not been addressed.

> Why is this happening? How do I stop it happening? Is it a lifestyle? is it diet? Is it reducing stress or whatever, whatever it is as though the general component to it. I want to get my licence back, I want to get my life back, because at the minute I haven't got that erm and I think that by effectively backing out and saying "You've got the thing in and it's working pretty, its working fine". We'll to me that's not the answer to me it's why is, why is it happening in the first place. (Participant F)

> I still have lots of questions erm and concerns, I think the attitude seems to be one of 'the implantation has been

successful, the system is working fine' therefore, that's it. (Participant B)

The participants felt that they needed more information, and felt that now that they had the ICD the level of support they received was not sufficient.

The participants identified that they need consistency regarding the advice given:

There has, there has be some, yeah there has, there's been confusing messages which have been given, again because I don't think anyone has picked up in terms of what the heart nurse says I can do, what the defibrillator clinic said or even what you want. So I don't think the consistency of message, I don't think has been there. (Participant I)

Participant K also identified uncertainty regarding what he could and couldn't do.

Hobbies, yeah I can't really, before I used to play golf and I don't think I can play anymore. I don't think I can go to the swimming pool and swim like I used to do.

In the above extract Participant K talks about not being sure whether he can play golf or swim. This uncertainty was also expressed by other participants for example Participant A, who talks about losing confidence due to not being given a definite answer regarding what he can and can't do.

I think, loss loss of confidence would be the biggest thing eh in terms of really not getting to grips with a feeling of what can I do and what can I do, can't I do is it driven by "you should not be doing that" or is it driven by "do that, if you feel like it." As soon as they say "do that, if you feel like it" if you have a rough night, you don't sleep very well, well funny old thing, you don't feel like it.

Tailored information

All of the participants expressed that everyone experiences living with the ICD and the ICD shock differently and, when it came to providing information to people with ICD's, this information should be tailored to the needs of the individual:

> No two people are the same, and they don't handle these situations the same, I do think that everybody's different, I do think, I'd probably say read up and ask questions, know exactly what is going to happen to you just know just know what you are going to expect. (Participant H)

Several highlighted that the way a person experiences a shock is unique to that person, one participant spoke about how the information he received regarding how a shock is experienced was not what happened in reality:

> D: a lot of them are American, it says, if you are in the street walking, and you have a shock, but only one,
> Interviewer: yes
> D: sit for a few moments and carry on as normal
> Interviewer: right
> D: well [laughs] there is no way that you can do that
> D2: where would you sit?
> Interviewer: so that hasn't been the case for you then?
> D: no, no, (Participant D)

They expressed a need for more tailored information, information that is more applicable to their circumstances, for example, when asked what advice they would give to someone about to have an ICD inserted, one participant stated*:*

> What advice would I give, it all depends on their circumstances, the same as anybody else, that if it is life threatening I would advise them to have it done, and I would definitely advise anybody to have it done if it was life threatening. (Participant L)

While another stated:

> I think that [advice to others] would depend on, why they were having it inserted. Ehm, I mean, if they had a, eh an attack before the episode, before they had it, then (2.0) ehm I don't think they would need much convincing as to why. (Participant F)

Several spoke about how it is difficult to provide the information about how people will experience a shock unless you have experienced it yourself:

> But I don't know if there is anybody that could of given me that kind of information, you know unless they had experienced it. (Participant A)

This was mirrored by Participant J who expressed that the most useful information he received was from other people who also had the defibrillator

> The most useful information I've received was from people that had had a defibrillator. Years before me, many years before me. And were still alive to tell the story. I was very impressed. (Participant J)

The Grounded Theory Model

This chapter has described the findings from this Constructivist Grounded theory study on how the experience of living with an ICD influenced patients and their partners' educational needs and concerns. According to Milliken and Schreiber (2001):

> When interpreting the stories of research informants and other data, a grounded theorist's goal is to construct a model to explain the action and interaction surrounding a phenomenon of interest. Thus, a grounded theory is the researcher's reconstruction of the participant's constructed definition and resolution of the situation and should be immediately recognisable to the participants in the study. (Milliken and Schreiber, 2001, p179)

Following the methods of grounded theory, the concepts identified were continuously and inductively developed from the data. Further, the concepts were arranged under progressively higher order subcategories. These subcategories combined to form one core category. This approach has been used to provide the basis for the development of the grounded theory model that emerges from the experiences of patients with ICDs and their partners.

The participants' acceptance of the ICD is influenced by how they got back to normal following the ICD implantation. Getting back to normal consisted of four sub-categories; adapting lifestyle, focusing on the positive, effect on the family and living with uncertainty. The order in which the categories were presented are not necessarily representative of the order in which they were experienced and while each patient experienced all four categories, they all experienced them to different degrees. This process of getting back to normal is influenced by how informed they feel regarding living with the ICD. The information the patient requires is influenced by their experience of the ICD and how they ultimately accept it in to their life. Contrary, the information they require is influenced by how the ICD impacted on them getting back to normal. Therefore the information a participant received should be tailored to the individual patient's needs.

An illustration of the full developed grounded theory model is shown in Figure 10 below.

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Figure 10: Grounded Theory Model: How the experience of living with an

ICD influenced patients and their partners educational needs and

concerns

Chapter 7

Discussion

The aim of this study was to develop an understanding of how the experience of living with an ICD influenced patients and their partners' educational needs and concerns. The grounded theory model outlined in chapter 6, demonstrates that the participants' acceptance of the ICD is influenced by how they got back to normal following the ICD implantation. This process is influenced by how informed they feel regarding living with the ICD. Also, the information they require is influenced by how the ICD impacted on them getting back to normal.

In this chapter, key findings from the study, namely acceptance of the ICD, adapting lifestyle and living with uncertainty will be discussed in relation to previous literature. I focus on adapting lifestyle and living with uncertainty as, while every participant spoke about all aspects of getting back to normal, the majority focussed mostly on adapting lifestyle and living with uncertainty. The model developed will then be compared and contrasted with crisis theory, uncertainty in illness theory and the common-sense model of illness. The model developed will also be discussed in relation to other patient education models and the concept of patient centred care. Finally, recommendations for the development of ICD patient education interventions and for further research will be presented.

The main findings were that when talking about their educational needs and concerns, all participants described their experiences around living with the ICD and how they ultimately came to accept their ICD in their life. The way they came to accept the ICD was by getting back to normal. To get back to normal following the ICD insertion, the participants spoke about adapting their lifestyle, dealing with the uncertainty, dealing with the effect on their family and focussing on the positive.

Key findings in relation to previous literature

Accepting the ICD

While patient education is important, the link between education and acceptance of the device is unclear (Sears et al. 2009). This current study identified that how the patient ultimately accepted the ICD was influenced by how the patient got back to normal (through adapting their lifestyle, dealing with the effect on the family, focussing on the positive and living with uncertainty) which in turn was influenced by how well informed they felt regarding living with the ICD.

Groeneveld et al. (2007) used the Florida Patient Acceptance Scale to study forty-five primary (prevention from happening) and seventy-five secondary (prevention from recurring) prevention ICD recipients. They identified that a patient's acceptance of the device does not appear to be

influenced by whether the ICD was implanted for primary or secondary preventative reasons. This current study also found that there was no difference between participants who had their ICD inserted for primary prevention and those who had their ICD inserted for secondary prevention.

Adapting Lifestyle

Since its first use in the 1980's, studies have been conducted looking at how patients adapt to living with the ICD. As previously stated in chapter 2, many of these studies focus on specific aspects of living with the ICD such as the impact on quality of life and dealing with the uncertainty around the ICD shock.

The main issues identified by participants in this study regarding adapting their lifestyle were work, driving and holidays. While it has been identified that the restrictions placed on driving following ICD implantation, and the ICD shock, impact adversely on Quality of Life (Johansson & Stromberg 2010) there is limited research focussing on the issue.

This study also found that the driving restriction placed on the ICD recipient adversely impacted on their lifestyle. The impact on a participants work life and holidays has not been the focus of any identified studies. Some early studies have highlighted that the ICD affects patients' ability to work (Dougherty et al. 2000). Participants in this

current study also spoke about how their ICD affected their work colleagues which has not been identified in previous studies. For example one participant spoke about how at work people treat her differently

> people treat me different because of it, especially in work as well, you know, sort of style, and I keep saying to them, I'm still the same person, I says I'm just slightly bionic! [laughs]. (Participant E)

While in the literature, sexual activity was also found to be a concern for ICD recipients, this was not mentioned by any of the participants in this study. This could potentially have been because either it did not adversely impact on their sexual activity or that they were uncomfortable talking about sexual issues with someone who was younger than them and who they did not know.

Living with uncertainty

Uncertainty is defined by Mishel as "the inability to determine the meaning of illness-related events." (Mishel, 1988, p225). According to Mishel uncertainty is a:

> Cognitive state created when the person cannot adequately structure or categorize an event because of the lack of sufficient cues. Uncertainty occurs in a situation in which the decision maker is unable to assign definite value to objects or events and/or is unable to predict outcomes accurately (Mishel, 1984, p225).

Mishel (1981, 1984, 1988) asserts that uncertainty in illness is present throughout the experience of the diagnosis, treatment and prognosis. Mishel (1990) posits that an individual will have difficulty adapting to an illness if they perceive the uncertainty surrounding their illness as a threat and that their coping strategies are ineffective.

One of the main findings in this study was the uncertainty the participants experienced regarding if and when they would experience shock. This influenced how they adapted to the ICD and subsequently their educational needs. Previous studies focussing on uncertainty have utilised quantitative methods, for example, several studies have utilised the uncertainty in illness scale. A study carried out by Flemme et al. (2005), found that uncertainty was related to reduced QoL in patients with ICDs at long term follow-up (M=6.9 years +/- 1). Mauro (2008 a, b) also found that greater uncertainty was linked to poor psychosocial adjustment and increased psychological distress. This current study looked at how they experience this uncertainty rather than just the level of uncertainty experienced.

Two qualitative studies focussing on the patient experience of the ICD found that the uncertainty surrounding having a shock was a major concern for ICD recipients (Eckert & Jones, 2002, Kamphuis et al. 2004). For example, the phenomenological study carried out by Eckert and Jones found that participants felt that they had no control over the timing

of the ICD shock. However, the three ICD recipients interviewed were all males and therefore their findings may not be applicable to females. However, although only 3 male ICD patients were interviewed, their findings were consistent with earlier studies such as Sneed and Finch (1990) and also a later study carried out by Kamphuis et al. (2004). My current study did not identify any difference between the male and female participants.

Kamphuis et al. (2004) interviewed both females (n=9) and males (n=12) and found that uncertainty around receiving a shock was experienced by both male and female participants. Even when no shock had been experienced participants experienced a fear of what the shock might be like. This was also found by my current study, for example, Participant L spoke about how even though her ICD had never discharged; she got apprehensive about the possibility of experiencing a shock.

> I do get apprehensive I think, just wondering if it is going to go
> off, but it has never went off

Comparison to other theories/models

Health psychology has developed from several other fields in the social sciences, and therefore the theories and models it utilises have been adopted and modified from other disciplines including clinical psychology, social psychology and behaviourism (Morrison & Bennett, 2009). Theory in health psychology is said to consist of "three broad types that vary

according to their generality: these are frameworks, theories and models"
(Marks, Murray, Evans & Estacio, 2011, p19). Marks et al. (2005) provide
definitions of the three types, frameworks are defined as, "a general
representation for conceptualising a research field or question" (p418)
theories as, "a general account of relationships between processes
believed to influence, cause changes is, or control a phenomenon" (p426)
and models as "an abstract representation of relationships between
processes believed to influence each other" (p421).   However, when
talking about theory in grounded theory research Charmaz (2006) asserts
that the term theory remains an ambiguous concept.   Charmaz claims
that while many grounded theory researchers claim to have developed a
theory, most of the studies are descriptive rather than theoretical.
Charmaz contends that grounded theorists should focus on the
meanings, actions and intentions of the research participants.   In
constructivist grounded theory study the result is more often presented as
a narrative rather than a theory and the focus is on developing an
understanding of social processes.   The main social process identified in
this study is how the patient ultimately came to accept the ICD.   This
study does not claim to have developed a theory; rather a descriptive
model with a narrative description.   While it is not essential in
constructivist grounded theory to develop a theory, it is essential that the
work and its findings are situated within the work of other theories and to
show how the work goes beyond, or adds to what is already known
(Stern, 2007). Therefore I will endeavour to position the findings from my

study and the model developed within current psychology theories with a focus on health psychology. The main theories and models I have identified that relate to my findings are the crisis theory, the uncertainty in illness model and the commonsense model of illness representations.

Crisis Theory

One of the main findings in this study is that to accept the ICD the individual needs to find ways to get back to normal and deal with uncertainty. Developed from Lindemann theory of grief reaction and Erikson's theory of psycho-social development, Caplans (1964) crisis theory is concerned with how people cope with life events and transitions. The theory specifically concentrates on the changes in self-identity and social identity a person experiences as result of a crisis. The theory states that people require a steady equilibrium to function and that the psyche cannot cope with a state of disequilibrium. Therefore when faced with this disequilibrium individuals employ coping methods in an attempt to regain equilibrium. Crisis theory was applied to health psychology by Moos and Schaefer (1984, 1993) who argued that a physical illness can be considered to be a crisis. In this current study there are two events that could be considered a crisis, namely the experience of the ICD insertion and the experience of the ICD shock.

Moos and Schaefer subsequently proposed a conceptual framework applying the crisis theory to physical illness. The aim of this conceptual

framework is to understand how people adapt to a life crisis such as a serious illness or injury (Moos & Schaefer, 1984, 1993). When faced with an illness crisis, Moos and Schaefer (1984) identify three coping processes: cognitive appraisal, adaptive tasks and coping skills.

Cognitive appraisal

Cognitive appraisal involves the person appraising the situation, however, no two people respond to the situation in the same way (Moos and Schaefer, 1984, 1993). They identify three sets of factors that can influence how they appraise and ultimately cope with a crisis event, namely personal and demographic factors such as their age and personal resources), social and environmental factors such as social support and other life events and finally illness related factors such as pain or disfigurement. Through this appraisal the person can apply coping skills to acquire basic adaptive tasks.

Adaptive tasks

Seven areas of adaptation within illness were identified divided into three illness specific tasks and four general tasks.

Illness specific tasks:
- Dealing with pain and incapacitation
- Dealing with hospital environment and treatment procedures
- Developing relationships with health professionals

General tasks:
- Preserving emotional balance
- Preserving satisfactory self image
- Preserving relationships with family and friends

- Preparing for an uncertain future

(Adapted from Moos, 1979; p9)

Moos and Schaefer (1984) contend that to deal with the illness crisis, following the appraisal of the threat and the utilization of the adaptive task, coping skills are accessed.

Coping skills

Moos and Schaefer (1984) categorise the coping skills into three types:

- Appraisal-focused coping – where the individual attempts to define and understand the situation.

- Problem-focused coping – involve the individual actively modifying the environment, by seeking information or dealing directly with the problem.

- Emotion-focused coping – involve engaging in strategies aimed at reducing the distressful emotional reaction brought on by the situation.

In the current study, following the 'crisis' of the ICD insertion, one of the ways the patients' got back to normal was by adapting their lifestyle. This could be classified as problem focused coping, as in Moos and Schaefer's definition of problem focused coping, the participants in my current study dealt directly with the problem by actively modifying their activities (for example changing their physical activity levels, or holiday destination) and also sought information to deal with living with their ICD, either from the cardiac team (nurse consultant etc) or via the patient

information on the internet. Another way the participants got back to normal following the ICD insertion or the ICD shock was by focusing on the positive which could be classified as emotion-focused coping, as the participants used humour to cope with the impact on their lives and also to focus on the fact that the ICD was potentially saving their lives. Appraisal focused coping was also employed by participants as they identified that they needed to feel informed regarding the device.

Moos, (1979) asserts that individuals are more susceptible to external influences during a life crisis than during a period of stability. It is assumed that patients are more likely to apply advice given by health professionals during a time when they are struggling to adapt to a crisis (a relapse or worsening of symptoms) and therefore health professionals can apply this model when they are helping patients through critical periods in their life, promoting effective adaptive behavior (Moos, 1979). In this current study the critical period identified by participants was following the insertion of the device and also following a device shock. During these periods participants were more likely to seek information, for example one participant spoke about how following the device insertion he needed to know what the implications of the device were going to be.

> If I know what I'm dealing with. I feel I can cope, it is the unknowns, and I don't cope with, well I don't know how you legislate for that, when you are dealing with lots of different people (Participant L)

Uncertainty in illness model

Mishel's (1990) uncertainty in illness model also looks at how people deal with uncertainty in illness and adapt to the illness. Mishel's model provides one way of understanding the relationship between the actual illness and how people adapt to the illness. Table 3, below is taken from Mast (1995) and provides an illustration of the four categories that form the basis of Mishels conceptualisation.

Table 3: Categories of variables forming the basis of Mishels model (Mast, 1995, p5)

Variable Category	Definition
Antecedents	Variables that precede or accompany, and influence uncertainty.
Uncertainty Appraisal	Recognition and cognitive classification of the uncertainty as neutral, as a threat or danger or as an opportunity.
Coping	Attitudes and behaviours used to manage the uncertainty.
Adaptation	Biopsychosocial adjustment within the individual's range of normal or usual behaviour. May include psychosocial adjustment, emotional distress, and quality of life

According to Mishel (1984) the characteristics of the illness situation, including the unpredictability, unfamiliarity and ambiguity, underlie the process of uncertainty. This study also found that, in many cases, participants were uncertain regarding the situation for example a few participants thought they were having a pacemaker rather than an ICD inserted which could be classified as ambiguous:

> I thought it was a pacemaker they were going to do to me
> but not really it was a defibrillator actually, I didn't know the

difference, between the one and the other (Participant N)

Participants Illness uncertainty has been found to be associated with poor adjustment. Furthermore it has also been found to be related to maladaptive coping, increased psychological distress, and a reduction in quality of life. The model put forward by Mishel proposes that coping is initiated to reduce uncertainty, particularly when there is a perception of danger. According to Mishel (1988) when a person believes that they have control over the situation, they are likely to use problem focussed coping strategies (for example looking for information, tackling the situation). However, should these strategies fail or if uncertainty is chosen over certainty (for example the uncertainty regarding a cancer relapse), individuals are more likely to use emotion-focussed coping strategies (for example wishful thinking, or escape avoidance).

In this current study, when it came to dealing with the ICD shock, participants felt that as they had no control over whether or not the device would fire, for example Participant D, spoke about how it didn't matter what he did, the device would fire:

> And if the thing is just as spontaneous as it appears to be, then, It doesn't really matter what I do, it well, it will either go off, or, or not go off according to how it's feeling not the activity I am doing, and as long as I'm not doing anything dangerous at the time. Then, that may be as good as it gets

As he had no control over the situation, he therefore utilised what Mishel would define as emotion focused coping, as he focused on the positive

aspects – the fact that as long as he was not doing anything dangerous, it would be OK.

The participants in this current study identified the need to feel informed regarding living with their ICD, for example

> The reasons why it has been done, don't be kind to me, tell me I'd rather deal with it straight, and that way if I have got concerns I can come back to you and let you know, (participant I)

The need to feel informed is a major part of the Uncertainty in Illness model and features in various categories including, antecedents (which includes familiarity with illness and symptoms) and problem focussed coping (which includes information seeking). A number of participants following the ICD implantation, on facing the uncertainty of living with the ICD employed problem focussed coping strategies by looking for information:

> I actually went on to the Internet to find out as much as I could about the procedures and everything like that. Because prior to its being fitted. I hadn't been told anything like that, I only got told about the procedures. (Participant B)

Lastly Michel (1984, 1988), identifies adaptation as a main category, which she defines as including psychosocial adjustment. In this current study, psychosocial adjustment could be categorised as adapting lifestyle where the participants make changes to their lifestyle to cope with the

impact of their ICD.   For example participants spoke about changing where they went on holiday and going to places where they have the facilities to reset the device:

> The machine I've got is a [name of device] and I went on their website, wherever you are going you can plug in and they will give you a list of any hospitals and clinics (Participant K)

Common-sense model of illness representations

Another model that focussed on how individuals cope with an illness threat is the common-sense model of illness representations (CSM). This model has several components to it and therefore I will only discuss those that could apply specifically to my model. The CSM, also known as the self-regulation model was developed by Leventhal, Meyer and Nerenz (1980) to explain how an individual processes an illness threat.   The interpretation of this illness threat is the first step in the process of seeking help, engaging in a coping strategy or adopting a self management approach. This interpretation is influenced by the cause of the threat, the consequences of the threat.

Following the diagnosis of a heart condition and insertion of the ICD, the recipient has to come to terms with an altered life situation (caused by the diagnosis of a cardiac condition and the ICD). In Leventhal's model this would be classified as an illness threat. It is assumed that when trying to understand the onset of illness or health threat, emotional responses and cognitive representations are generated.   In the current study the

cognitive representations relate the reason for the ICD insertion (causes) and the lifestyle implications (consequences). For example participants spoke about the reasons for the ICD implantation which in many cases was to save their life:

> And he said 'you require this' and I asked why and he said, 'because you'll die if you don't' (Participant F)

As participants have no control over the ICD, to try to regain a state of equilibrium they sought to find ways to cope with these responses and representations.

As with both the Uncertainty in Illness model and the Crisis theory, the coping styles include problem-focused coping and emotion focused coping as well as strategies such as seeking social support and avoidance/denial. The coping style a person selects is believed to be linked to the type of representation they generate. Finally the individual appraises these coping methods and makes the necessary adjustments – either continuing with the current coping style or adopting an alternative one.

Figure 11, below is taken from Hagger and Orbell (2003) p144
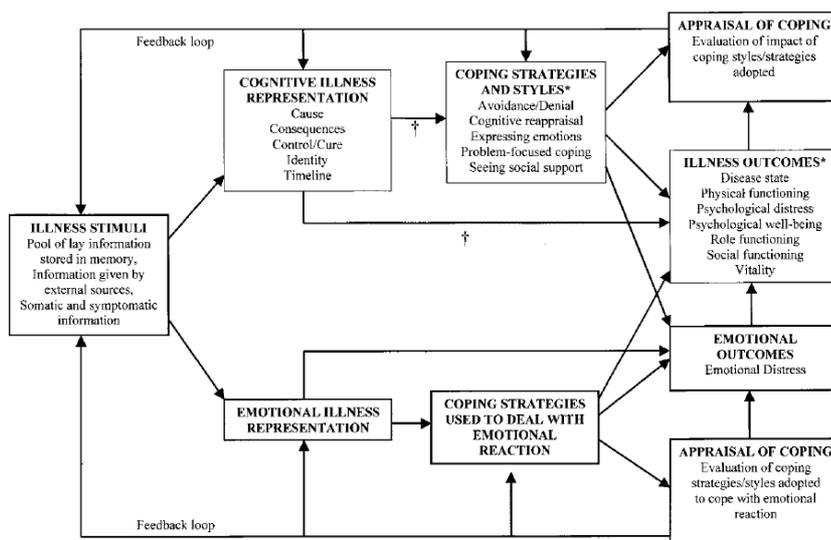
Figure 11: A diagrammatic representation of Leventhal et al's (1980, 1984) Common Sense Model of Illness Representations.

Leventhal et al. (1980, 1984) assert that three sources of information influence a person's illness representation. The first source of information is from significant others (for example a parent or spouse) and authority figures such as a doctor. The second source is the cultural and social information the individual already has regarding the illness – the lay knowledge they have. The final source of information comes from their current experience of the illness, and the knowledge they have of their previous efforts to cope with the illness

In this study how the participant ultimately accepted the ICD was influenced by the information the ICD patient and their partner received and also influenced the information they required. For example, the participants required information that was tailored to their individual needs

and their individual needs were influenced by their experience getting back to normal following ICD implantation. Furthermore, the participants identified that the information they received was not adequate, which influenced how they got back to normal, and adapted their lifestyle, for example a number of participants were not told about the impact it could have on their holiday destinations, and one subsequently lost a holiday due to this.

The grounded theory model developed in this current study does not include appraisal of coping style, however further research focusing on the categories developed in this study could potentially lead to the development of a model that includes how the individual appraises how they 'get back to normal' following their ICD implantation.

Patient education models

Central to the findings in this study was how the patient adjusted to the ICD and 'got back to normal'. This patient adjustment influenced the educational needs they had and was influenced by the patient education they received. As this is a qualitative study, the exact nature and strength of this influence cannot be determined, however studies have found that there is a link between patient education and acceptance of the ICD. For example, both Sears et al. (2009) and Kuhl et al. (2009) assert that lack of knowledge regarding the device impacts on a patient's ultimate

acceptance of the ICD and adequate patient education can play a key role in maximising the acceptance of the device.

Patient Centred Care

Originally developed under the name client-centred therapy by the humanistic psychologist, Carl Rodgers in the 1950's (Rogers, 1951), it was introduced by psychoanalyst Balint (1969) to medicine under the term "patient-centred medicine." Balint defined patient-centred medicine as "understanding the patient as a unique human being" (Balint, 1969, p269). However even though the concept is used extensively in health care and psychological literature, there is little consensus regarding its definition (Huddon et al. 2011). The Institute of Medicine (2001) defined patient-centred care as:

> Providing care that is respectful of and responsive to
> individual patient preferences, needs, and values, and
> ensuring that patient values guide all clinical decisions
> (Institute of Medicine, 2001, p3)

Respect for patients' values, preferences, and expressed needs, means that patients have the opportunity to be informed and involved in the decisions relating to their care. This respect is reflected in the NHSScotland Quality Strategy (Scottish Government 2010). The Quality Ambitions outlined in the Quality Strategy are based on the Institute of Medicines six dimensions of Quality. One of the Quality Ambitions is that the healthcare system should be person-centred, consisting of:

> Mutually beneficial partnerships between patients, their
> families and those delivering healthcare services which

respect individual needs and values and which demonstrates compassion, continuity, clear communication and shared decision-making (Scottish Government, 2010, p23)

Furthermore, the Institute of Medicine also asserts that:

Patients should be given the necessary information and opportunity to exercise the degree of control they choose over health care decisions that affect them. The system should be able to accommodate differences In patient preferences and encourage shared decision making (Institute of Medicine, 2001, p4)

Following a review of the theoretical and empirical literature, Mead and Bower (2000), developed a model of the diverse characteristics of the doctor-patient relationship included in the conception of patient-centred care. The following five dimensions were identified: biopsychosocial perspective, patient-as-person, sharing power and responsibility, therapeutic alliance and doctor-as-person. Stewart et al. (2000) proposed six dimensions: exploring both the disease and the illness experience, understanding the whole person, finding common ground, incorporating prevention and health promotion, enhancing the patient-doctor relationship, and being realistic. Hudon et al. (2011) combined the two frameworks, keeping the four common dimensions. Figure 12, below, provides an illustration of Hudon et al's combination of the frameworks.
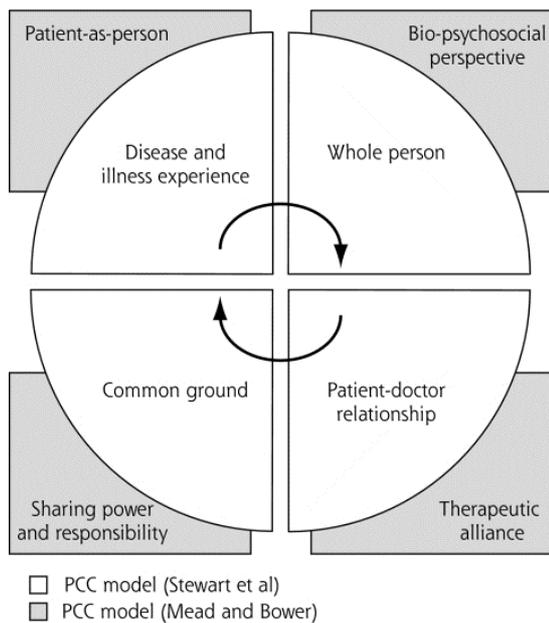
Figure 10: Combination of Mead and Bower and Stewart et al's frameworks (Hudon et al. 2011, p156)

Essential to both of these models is the biopsychosocial perspective (called "understanding the whole person" in Stewart et als' model) and the experience of the illness or disease (called "Patient as Person" in Mead and Bowers' model). Central to the grounded theory model developed in this study was how the patient got back to normal following the insertion of the device. It was the patients' experience of this and how it impacted on all aspects of their life (biopsychosocial perspective), and how they came to accept the device that ultimately informed their educational needs.

The provision of accessible and high quality patient education which will empower patients to make informed choices is the focus of both current English government policy (Department of Health, 2010) and Scottish

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Government policy (Scottish Government, 2010). Garner, Ning and Francis (2011) assert that patient information leaflets play a central role in this. However, in an opinion piece in the British Medical Journal, McCartney (2013) asserts that while the NHS is inundated with patient information, generally in the form of leaflets, these leaflets are "inaccurate, inconsistent, and confusing – and effort is duplicated" (p4748). Pander Maat and Lentz (2010) assert that how people respond to healthcare information depends on how this information is presented. With regards to their health people generally to want to know (1) what is wrong (diagnosis) or how to stay well, (2) what is likely to happen and how it will affect them and (3) what can be done with regards to treatment or management of their condition (Institute of Medicine, 2001). They need answers that are both accurate and understandable.

This current study highlighted that the information received was not presented in a consistent way. For example one participant stated

> there's been confusing messages which have been given, again because I don't think anyone has picked up in terms of what the heart nurse says I can do, what the defibrillator s clinic said or even what you want. SO I don't think the consistency of message, I don't think has been there (Participant B)

This inconsistency of information lead to some patients expressing that they experienced anxiety. Patient concerns about the ICD have been found to be a determinant of anxiety and depression (Pedersen et al. 2005). One of the main concerns Pedersen et al (2005) identified was

fear regarding whether or not the ICD will fire. However these concerns were independent of whether or not they had actually received a shock (Pedersen et al 2005). While this current study did not measure rates of anxiety among its participants, a number indicated that they experienced anxiety generally around the uncertainty around if and when they were going to experience a shock. Furthermore, both patients who had received a shock and patients who had not received a shock expressed this anxiety.

Sears et al (1999) highlights that anxiety is common in ICD recipients and the experience of ICD shocks is usually indentified as the reason for this. Receiving education and psychosocial support has been found to improve this anxiety, for example a number of studies including Frizelle et al, (2004), Bostwick and Sola (2007), Sears et al (2007) and Lewin et al (2009) all reported improved psychological adjustment following a behavioural or psychosocial intervention. For example Frizelle et al. (2004) examined the effect of a 6-week cognitive behavioural intervention on both the occurrence of shock and reported anxiety.   One of the main findings was that anxiety was significantly reduced at both 3-month and 12-month follow-up.

Child, Sanders, Sigel and Hunter (2010) carried out a study to develop a service to meet the psychological needs of cardiac patients. While not specifically focussed on patients with ICDs, the intervention focuses on

cardiac patients in general, the majority of patients who have ICDs have an underlying heart condition. Therefore the stepped-care model employed, namely offering a range of psychological treatments to meet the needs of each specific cardiac patient depending on severity and psychological need, could be adapted to include ICD specific information. Furthermore the programme developed by Child et al. (2010) is menu driven where the patient is assessed by a psychologist and supported to choose the intervention that is most suitable to them. This way patients with higher psychological needs access a more intense intervention with more psychological support whereas those with lower psychological needs could access a less intense intervention. From a systematic review carried out by Magyar-Russell et al. (2011), looking at the psychological responses to ICD insertion, it is evident that responses are varied and range from experiencing clinically significant high anxiety and/or depression to low anxiety and/or depression. Furthermore, a number of studies have identified that a patient can experience varying levels of anxiety and depression over time following implantation of the device (Sears & Conti, 2003; Bostwick & Sola, 2007; Pozuelo et al. 2009). Other variables that have been found to impact of anxiety levels include experience of device shock (Maryniak et al, 2007; Jacq et al. 2009) and whether the patient had the ICD inserted for primary or secondary preventative reasons (Pedersen, Hoogwegt et al. 2011), This therefore has implications for health professionals and both Pedersen, den Broek et al (2011) and Dunbar et al (2012) assert that

these professionals need to be aware of this and routinely assess the patients' psychological status and concerns.

This current study did not find any difference in the expressed anxiety levels of patients who had had a device shock, compared to those who had not, nor was any difference found between those who had the device implanted for primary preventative reasons versus those who had had the device implanted for secondary preventative reasons.   However, no empirically based measure of anxiety was employed, therefore whether they experienced clinically significant anxiety cannot be definitively determined. Nevertheless, participants expressed that they experienced anxiety and the levels of anxiety varied between the participants. Therefore there is a case for routinely assessing anxiety levels to determine the level of support each individual patient requires.

Tailored Communication

Tailored communication is defined by Stellefson, Bruce, Chaney and Chaney (2008) as;

> a combination of information/change strategies intended to reach one specific person, based on the characteristics unique to that person (p303)

 Compared to generic information, tailored information is more likely to be read, remembered and viewed as personally relevant (Kreuter and Wray, 2003)]. Moreover, it enables individualized feedback, commands greater attention, is processed more intensively, contains less redundant

information, and is perceived more positively by health consumers (Noar, Banac & Harris, 2007).

Each patient is different and will interact differently with the health care system, while some need to interact with the health professionals regularly and build up an ongoing relationship with them, others only want to interact with the health professionals when absolutely necessary (Institute of Medicine, 2001). However, all patients want information that they can trust in a manner that is tailored to their individual needs (Institute of Medicine, 2001).

This current study identified that patient education should be targeted to helping the patient get back to a normal life and ultimately accept the ICD. This education should be tailored to their individual needs and also be adequate (relevant and appropriate at that particular time) for their needs. Both Steinke et al. (2005) and Tagney et al. (2001) also found that ICD patients need information specific to their particular needs. For example one participant stated that they would have liked more information before the implantation:

> I would have liked to have known more about the procedure
> before you go in I think that they could have been, maybe
> more of a leaflet that could tell you exactly what's going to
> happen (Participant C)

However while studies have found that tailored messages are more effective than non-tailored messages, the time and resources involved in creating the resources means that the effects of the resources needs to

be large enough to merit this (Halder, et al, 2006, Noar et al 2007). To assess whether tailored interventions were effective a meta-analytic review of 57 studies on tailored print health behaviour change interventions was carried out by Noar et al (2007). They found that tailored interventions were more effective than non-tailored interventions and further identified that a number of variables moderated this effect, including the health behaviour, type of participant population, number of intervention contacts, type of print material and length of follow-up. Specifically interventions that included pamphlets, newsletters or magazines were found to be more effective than those that used letters or manuals. They also suggest that tailored interventions could incorporate modern technologies such as websites, electronic mail and text messages.

Identifying patient preferences for receiving support and education is essential as it leads to the patient having their needs and concerns addressed in the most suitable way for them (Serber et al. 2009). This in turn leads to increased adherence to medical regimens, improved quality of life and improved outcomes for the patient (Serber et al. 2009). A nonexperimental cross- sectional study using questionnaires carried out by Serber et al (2009) looked specifically at the preferences for receiving support and education among patients with ICDs. They found that different groups of ICD patients prefer to receive education and support in different ways. Specifically they found that women preferred receiving

support from other ICD patients, or health professionals and that younger ICD patients (aged less than 67 years) expressed a preference for receiving support and education via online modalities (i.e. websites and chat rooms). They assert that while it is difficult for health professionals to provide the individualised care they need (due to the increased numbers of ICD patients, time limitations etc), by having standard protocols in place in different formats (face-to-face, telephone, Internet Website, written etc) and offering the patient the choice of modality may improve patient quality of life and healthcare outcomes.   However due to the ,limited sample size (n=108) and the fact that the sample was recruited from only two clinic sites in South Carolina, the results have limited generalisability and therefore further larger studies are required. In this current study patients various formats for the delivery of the information were identified namely written, face-to-face (either by health professionals or other ICD patients), telephone, or the internet, with face-to face being the preferred option, though a number of participants also accessed the internet to supplement the information they received from health professionals.

Health information has been found to be one of the most frequently sought topics on the internet. While the internet has made it possible for patients and their families to access large quantities of information, health information websites are recognised to differ widely in quality and reliability of their content. A number of participants in this current study

accessed the internet to acquire information regarding their ICD, for some

this was the only information they got prior to having the ICD fitted and

they found it really helpful:

> I was told that I'd get a date to come in to have it fitted,
> that's when I actually went on to the Internet to find out as
> much as I could about the procedures and everything like
> that. Because prior to its being fitted. I hadn't been told
> anything like that; I only got told I was getting it fitted.
> (Participant C)

While others did not find the internet as helpful as the sites they accessed

focused on things that could go wrong:

> I found out web sites on the Internet with people that it had
> them fitted, problems they were going through, feelings
> that they had and I found myself, feeling kind of worried
> (Participant E)

Therefore it is important that health professionals signpost patients to

reliable websites that are appropriate for their individual needs (Ward &

Leach, 2012).

Appraisal of study quality

To appraise the quality of my study I applied the CASP framework, as

outlined in Appendix 1.

The aim of the study was to develop an understanding of how the

experience of living with an ICD influenced patients and their partners

educational needs and concerns. A qualitative methodology was

employed as the question guiding the study was both open-ended and

exploratory namely how the experience of living with an ICD influences the educational needs and concerns, Furthermore as there is little qualitative research focusing on this area a qualitative research design is appropriate method to employ.   A constructivist grounded theory approach was employed as the aim was to move beyond in depth exploration of a situation, and instead try to understand how the experience of living with an ICD influenced their educational needs

Regarding the recruitment strategy employed, while the sample was purposeful and taken from one ICD support group, the support group I recruited from was the only support group in Scotland and therefore comprised of patients from all over Scotland.   Although in qualitative research each participant's story is considered unique and the intention is not to generalise the findings, they are considered more reliable if they can be applied to other ICD recipients and the findings resonate with them (Creswell, 2012). In addition as the constant comparative method of grounded theory was employed, recruitment was continued until the categories were deemed saturated. In this study saturation was reached before all the interviews had been carried out and confirmed by the last two participants. This increases the plausibility and validity of the results. Finally, the participants were all happy to talk to me and a number expressed that they appreciated having the time to talk about their experiences.

However, while I was able to speak to female partners of ICD recipients, I was unable to recruit any male partners. When I went to interview the female participants, their partners were either not there or said that they would have nothing to say in an interview, as they were not affected by their partners ICD. For example one participant when talking about her husband stated "he doesn't like to participate in these things [interviews]" (Participant B).   To try to address this problem of non participation by the male partners I asked the question in the interview, how has your partner coped with your ICD, and also asked if their partner had had any question for the medical staff regarding the ICD. However, generally when asked this question, the participants stated that other than being a bit more protective, their husbands did not seem to be affected, or have any questions, for example, one participant stated:

> he was overprotective, the first time I went abroad without him
> he told the guy I was travelling with that I was not to lift a bag
> and you know these were the only conditions I was going but
> all that has settled a bit (participant C)

This study utilised interviews as the method of data collection. Interviews are employed when the researcher's goal is to capture feedback on personal experiences or when there is anything sensitive about the experience that participants may not feel comfortable sharing in front of other people in a focus group situation (Seidman, 2010).   In this study I was looking at how the experience of living with the ICD affected participant's educational needs and concerns, this was a personal experience for each participant, and it also could have identified some

potentially sensitive issues that participants may not have self comfortable disclosing in a focus group situation, therefore interviews were most suitable for this study.

My background working in the centre of cardiac care and education at York University lead to me developing an interest in cardiac conditions and discussions with researchers in the field of cardiac care helped me to identify that the educational needs of patients with ICDs as a topic that had not been focussed on in the research. Furthermore, as discussed in chapter 4, I realise that being at least 20 years younger than the participants could have influenced my relationship with the participants, however I have had experience working with older people and dealing with sensitive topics.

Regarding ethical issues, as discussed in chapter 5, ethical approval was obtained from the Queen Margaret University ethics committee. Prior to the interview, through providing an information sheet and discussing the study with the participants (including giving them time to ask any questions) I ensured that the participants were fully informed regarding the study including the voluntary nature of the study, what would be involved should they decide to participate, how the data would be stored and what the data would be used for.   The information sheet provided to participants and also the consent form are located in appendix 5 and 6 respectively,

Following the constructivist grounded theory process; data analysis was conducted in a systematic but non-linear fashion using the constant comparative technique. While I initially carried out the qualitative data analysis manually, during the focussed coding process I transferred the interview transcripts and the data codes into NVivo. This enabled me to interact with the data (the interview transcripts and the memos) more easily as I was able to manage, and combine the initial codes more effectively which assisted me in the development of the initial codes and the final categories and core category.

As discussed in chapter 6, my main finding was that the participant's acceptance of the ICD is influenced by how they got back to normal following the ICD implantation. This process of accepting the ICD is influenced by how informed they feel regarding living with the ICD. Also, the information they require is influenced by how the ICD impacted on them getting back to normal. To describe the model I developed I provide both a diagrammatic representation and a narrative description.

Finally, in chapter 7, I discuss my findings in relation to previous research and also current practice. The main findings discussed are in relation to accepting the ICD, adapting lifestyle (namely work, driving and holidays) and living with uncertainty.

Conclusions

One of the main tasks in health psychology research is to identify and understand the factors that influence a person's concordance to medical treatment or self management programme and to identify suitable targets for intervention (Leventhal et al. 1984; Petrie et al. 1996). The aim of this thesis was to develop an understanding of how the experience of living with an ICD influenced patients and their partner's educational needs and concerns. When talking about their educational needs and concerns, patients with ICDs main need is to get back to normal and ultimately accept the ICD in their life. To do this they need information that is tailored to their individual situation.

One of the main contributions of this study was that it focused on the holistic experience of the ICD patient. Other studies generally focused on one aspect of living with the device, for example the anxiety experiences, lifestyle implications or quality of life implications. This focus on the holistic experience was most valuable when they spoke about living with the uncertainty regarding the device shock. While a number of quantitative studies have looked at the uncertainty around the device shock, few qualitative studies have done so. By focusing on how the patient experienced the shock rather than the quantitative aspects (level of uncertainty, predictors of uncertainty etc) it provides a depth of data

that is most useful when developing and tailoring patient education materials.

Another contribution is the study showed that each patient experienced living with and ultimately accepting the ICD in a unique way. Each participant experienced living with the ICD differently though all focused on how they got back to normal following the ICD insertion. The implications of this are that health professionals therefore cannot treat patients with an ICD as an homogenous group and therefore cannot have one specific type of patient education to suit all ICD patients.

Recommendations for further research

Further qualitative research is needed to explore how ICD patients appraise the process of getting back to normal, thus identifying whether they thought their coping processes were healthy or maladaptive. This information could further inform patient education materials.

Few studies have also included the experiences of partners of ICD patients, and while this study only included 4 partners, it was identified that they were affected by their partners ICD. Therefore research is needed to further explore their educational needs and concerns.

Implications for practice

This study identified each ICD patient experienced living with the device differently and required different information at different times. How they ultimately accepted the ICD was influenced by this. Therefore each patient requires information that is tailored to their individual needs and experiences. When developing patient interventions or education materials, the health professionals should take the patients' individual needs and experiences into account.   While each participant experienced living with the ICD differently, all had the same main questions, namely, why am I having the ICD inserted and what is it going to mean for me. Therefore, when providing patient education these are the areas a health professional should focus on.   Furthermore, having standard educational resources in place in various formats (written, Internet Website, CD-ROM) would mean that patients can access the resources they require in the format they prefer.

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Appendix 1

CASP Screening Questions

1. Was there a clear statement of the aims of the research
2. Is a qualitative methodology appropriate?
3. Was the research design appropriate to address the aims of the research?
4. Was the recruitment strategy appropriate to the aims of the research?
5. Were the data collected in a way that addressed the research issue?
6. Has the relationship between researcher and participants been adequately considered?
7. Have ethical issues been taken into consideration?
8. Was the data analysis sufficiently rigorous?
9. Is there a clear statement of findings?
10. How valuable is the research?

(Public Health Resource Unit 2006)

Appendix 2
Transcript Included in Support Group Newsletter

This Project has Ethical Approval

My name is Julie Ferguson and I am a Health Psychology Doctorate Student at Queen Margaret University. As part of my course I have to carry out a research project and, after discussion with staff at Chest Heart and Stroke Scotland, I have decided to interview people who have had Implantable Cardioverter Defibrillators inserted and their partners. The interview will be to find out what concerns people have regarding the ICD, what knowledge they have about their ICD and what information they would like to have been told before and after having the ICD inserted. The information you give will assist the health professionals to understand the needs and concerns of patients and help them with the development of services for people with ICD's.

The information you give will be completely confidential and you will remain anonymous. The interview will last between 45 minutes and 1 hour, and will be in a location suitable for you. You will be asked questions about the information and support you/your partner was given, how your life has changed since you/your partner had the ICD inserted, and how the ICD has affected you and your family. The interview will be taped, but the tape from your interview will only be available to my supervisor and myself. Once the interview has been transcribed, you will be sent a copy to read through and comment on and the tape will be destroyed. You will not be able to be identified from the transcription.

Participation in this study is VOLUNTARY. You are under no obligation to take part in it and you have the right to withdraw at any time. You are also free to withhold any information you are not happy to disclose. If you agree to take part though, it is important that you answer the questions in the interview as fully as possible.

If you have had an ICD inserted within the last 5 years or your partner has had one inserted within the last 5 years and you would like to take part in the study or have any questions regarding this study, my contact details are provided below. Or, if you would like to speak to a member of staff at Queen Margaret University, Dr. Joyce Willock (tel 0131 317 3610) is available to speak to you.

Thank you for your time

Julie Ferguson

Telephone: 0131 317 3397
E-mail: jferguson@qmu.ac.uk

Appendix 3

Ethical Approval Form

APPLICATION FOR ETHICAL APPROVAL

FOR A RESEARCH PROJECT

This is an application form for ethical approval to undertake a piece of research. Ethical approval must be gained for any piece of research to be undertaken by any student or member of staff of QMUC. Approval must also be gained by any external researcher who wishes to use Queen Margaret students or staff as subjects/participants in their research.

You should read QMUC's chapter on "Research Ethics: Regulations, Procedures, and Guidelines" before completing the form. This document is available from the Secretary to the Research Ethics Committee or on the QMUC IT network, in the Public Folders of Outlook.

The person who completes this form (the applicant) will normally be the Principal Investigator (in the case of staff research) or the student (in the case of student research). In other cases of collaborative research, e.g. an undergraduate group project, one member should be given responsibility for applying for ethical approval. For class exercises involving research, the module coordinator should complete the application and secure approval.

1. Name of applicant

……………Julie Ferguson……………………………………………………………

2. Title of project

The informational needs and concerns of patients with Implantable Cardioverter Defibrillators

3. Affiliation of applicant:- please tick box
Queen Margaret undergraduate student
Queen Margaret postgraduate student - taught degree   X
Queen Margaret postgraduate student - research degree
Queen Margaret staff - research degree
Queen Margaret staff - other research
Other (please specify and give contact details)

4. Are you the director of the research?   ~~Yes~~/No
Students should answer 'No' to this question. If you answered 'Yes', go straight to section 6.

5. Give the name of the director of the research or, in the case of research to be carried out as a student, the name of your supervisor or Director of Studies

……Michele Hipwell……………………………………………………………………

6. Give the names and affiliations of any other researchers who will be working on the project.

   None…… …………………………………………………………………………….

7. Give details (amount and source) of any financial support, from outside QMUC, for the project.

   …None……………… ……………………………………………………………………

8. When is the project likely to start and when is it likely to end?

   ………………March 2006 – March 2007……………………………………………….

9. What are the aims of your research?

The aims should be stated briefly and in terms that a lay person could understand.

   To identify, through interviews, the current knowledge and informational needs of patients who have had an implantable cardioverter defibrillator inserted and their partners/carers

10. Does your research include the use of people as participants/subjects?   Yes/~~No~~

If you answered 'No' to this question, go straight to section 18.

11. Will any of your subjects/participants be NHS patients (recruited in their capacity as NHS patients)?   ~~Yes~~/No

QMUC cannot grant approval for research involving NHS patients. Approval must be sought from the relevant NHS Ethics Committee. You should familiarize yourself with NHS Research Governance Framework. When such approval is obtained, it will be accepted by QMUC as covering all subjects described in the submission to the NHS committee, including any non-NHS subjects. A copy of the final letter of approval from the NHS Ethics Committee must be sent to the Secretary to the QMUC Research Ethics Committee.

If you answered 'Yes' to this question and you intend to submit an application to an nhs research ethics committee, see section 12 and then go to section 18.

12. Will any of your subjects/participants be NHS employees (recruited in their capacity as NHS employees)?   ~~Yes~~/No

QMUC cannot grant approval for research involving NHS employees. Approval must be sought from the relevant NHS Ethics Committee. You should familiarize yourself with the NHS Research Governance Framework. When such approval is obtained, it will be accepted by QMUC as covering all subjects described in the submission to the NHS committee, including any non-NHS subjects. A copy of the final letter of approval from the NHS Ethics Committee must be sent to the Secretary to the QMUC Research Ethics Committee.

If you answered 'Yes' to this question and you intend to submit an application to an nhs research ethics committee, go straight to section 18.

13. Indicate below the source and estimated number of your subjects/participants.

If your research is a case study of an individual, write "individual case study" under 'Number'.

Source Number
Queen Margaret students   0
Queen Margaret staff   0
Non-Queen Margaret (please describe)   Individuals attending a support group for people with ICDS and their carers will be approached, the reason for the interview will be explained and they will be asked if they wish to participate. With grounded theory, the process of data collection (interviewing) and data analysis continues until theoretical saturation has been achieved (theoretical sampling). Therefore, the exact number of participants cannot be ascertained. It is estimated that approximately 20 participants (10 patients and 10 partners) will be interviewed.

14. Will you be able to obtain the consent of your subjects?   Yes/~~No~~

If you answered 'No', explain the reasons and describe the measures you will take to safeguard their rights and minimise any risks. If you answered 'Yes', describe how you will select and approach your subjects and how you will obtain their informed consent. You should attach a copy of the Information Sheet that you will give to people who you ask to participate. This should explain as fully as possible and in terms meaningful to a lay person what the research is about, why it is being undertaken, who is undertaking it, and, if relevant, who is financing it. If the nature of the research is such that fully informing potential subjects before the study would invalidate results, then whatever explanation is possible should be given, and there must be provision for appropriate explanation to the subjects on completion of the research. The Information Sheet should normally include the name of a responsible person who is not part of your research project and who subjects or potential subjects can consult for independent information. The nature of any promise of anonymity, confidentiality, or restriction on the use of information must be made clear and strictly adhered to. Signature on a Consent Form is the usual way of recording informed consent by the subject. An example of a Consent Form and an Information Sheet can be obtained from the Secretary to the Research Ethics Committee or from the QMUC IT network. In the case of child subjects, or adult subjects whose ability to give informed consent may be doubted, a third party (usually a parent or guardian) should be involved in the process. Where subjects are obtained from an organisation (e.g. a school, another university, or a workplace) the approval of that organisation should be assured. In the case of schools, it may be necessary to obtain permission from the Local Education Authority as well as the head teacher. The subject should be informed that they have the right to withdraw their participation at any time, without giving a reason, and this right must be respected.

15. Will your subjects be identifiable in any records, presentations or reports of the research?

~~Yes~~/No

If you answered 'Yes', give further details, including information about location of storage and length of time before destruction.

…………………………………………………………………………………..

16. Will any payment or reward be made to the subjects, beyond reimbursement of out-of-pocket expenses?   ~~Yes~~/No

If you answered 'Yes', give details.

………………………………………………………………………………………….

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17. Give a brief description of your research method and procedures.

In this section, pay particular attention to any invasive procedures, any potential hazards or discomfort to subjects, or any distress or embarrassment they may experience, and describe the measures you will take to minimise risks.

Participants: The participants will be recruited from ICD support groups. CHSS has identified that patient education of ICD patients and their families is necessary and a study identifying the concerns and educational needs of ICD patients is therefore required. This study will therefore be conducted with the support of CHSS. Grounded theory has been identified as the most appropriate method of analysis for this study and with grounded theory, the process of data collection (interviewing) and data analysis continues until theoretical saturation has been achieved (theoretical sampling). Therefore, the exact number of participants cannot be ascertained. It is estimated that approximately 20 participants (10 patients and 10 partners) will be interviewed.
Methodology: This study will employ qualitative methodology to explore ICD patients and their partners' knowledge and informational needs. Qualitative methodology will be used as it allows the researcher to "stay closer to their data and to the surface of words an events" (Sandelowski 2000). A semi-structured interview will be used where open-ended questions will be used to guide, but not lead, the interview. Patients and carers will be encouraged to speak freely about the questions and raise other issues and concerns to ensure that all of their concerns and educational needs emerge during the interview. The interview schedule has been included for both the patients and their partners.

Procedure; Recruitment will be carried out at the support group. With the support of the workers at the support group, the potential participants will be informed (either verbally or through posters) of the study and what participation involves and asked if they wish to participate. Those wishing to participate will be assessed for eligibility.

Eligibility criteria will be:
Patients: ICD inserted between 3 and 24 months ago
Carers/partners: Either a carer or partner living with a patient who has had an ICD inserted 3-24 months ago.

Consent will be obtained from each participant and confidentiality will be assured. Patients will also be made aware of their right to withdraw from participation at any time, without having to give a reason. Time before the interview will be set aside to answer any questions the participant may have. The interviews will be conducted at a time

suitable for the participant, and will last approximately 45 minutes – 1 hour. Interviews will be conducted in a quiet and comfortable setting, where there will be little chance of interruption.

Interviews will be audio recorded this will allow for uninterrupted attendance and interaction with the interviewee as well as providing a complete record for data analysis. The tapes will be transcribed verbatim. The transcriptions will then be sent to the participant to ensure that no discrepancies have occurred and that the participant agreed with the transcription and once the participant has agreed with the transcription the tape will be destroyed.

The researcher is aware that studies conducted with people with a chronic illness and the relatives of people with a chronic illness must be conducted sensitively and several steps will therefore be taken to ensure the study will be conducted ethically

1) The participants will be given time to ask questions about the study, to ensure that they understand fully about the research and what will be involved.
2) Informed consent will be obtained and confidentiality will be assured.
3) Participation will be voluntary and the participants will be assured that they will be free to withdraw at any time without giving a reason.
4) Prior to the interview the researcher will inform the participant they do not have to answer any questions they do not want to.
5) The questions asked in the interview are ones that are routinely asked in hospital and similar research. However, should the participant become upset in any way the interview will be stopped and the participant will be referred to either the support group or their general practitioner for further help.

<u>Analysis</u> The study will be informed by grounded theory, which involves simultaneous data collection and analysis, together with systematic efforts to check and refine developing categories of data. This method has been chosen, because it allows for the generation of a model or theory within a more or less unknown area, based on statements made by patients with ICD's and their partners/carers.

18. Does your research involve the experimental use of live animals?　　~~Yes~~/No

Research involving animals is likely to be outwith the remit of the QMUC Research Ethics Committee. If you answered 'Yes' to this question, you should consult the secretary to the committee about how you should proceed.

19. Does your research involve experimenting upon plant or animal matter or inorganic matter?　　　　　　　~~Yes~~/No

If you answered 'Yes' to this question, you should state the source of the material and whether you foresee any potential adverse impact on the environment or any hazards to people (including the researchers themselves) and, if so, the measures you will take to minimise the risks.

20. Does your research include the analysis of documents, or of material in non-print media, other than those which are freely available for public access?　　~~Yes~~/No

If you answered 'Yes' to this question, give a description of the material you intend to use. Describe its ownership, your rights of access to it, the permissions required to access it and any ways in which personal identities might be revealed or personal information might be disclosed. Describe any measures you will take to safeguard the anonymity of sources, where this is relevant.

21. Will any restriction be placed on the publication of results? ~~Yes~~/No

If you answered 'Yes', give details and provide a reasoned justification for the restrictions.

………………………………………………………………………………………….

………………………………………………………………………………………….

………………………………………………………………………………………….

………………………………………………………………………………………….

22. Having completed all the relevant items of this form and, if appropriate, having attached the Information Sheet and Consent Form, sign the statement below.

I have read Queen Margaret University College's chapter on "Research Ethics: Regulations, Procedures, and Guidelines". I request Ethical Approval for the research described in this application.

Signed ____*Julie Ferguson*_____ Date _25/03/06___

Unless you are a student, go straight to section 24

23. Show the completed form to your supervisor/Director of Studies and ask them to sign the statement below.

I am the supervisor/Director of Studies for this research. I have read this application and I approve it.

Signed _____ Date _____

24. Hand the completed form to your Head of Subject or Head of Research Centre or, if you are an external researcher, submit the completed form to the Secretary to the QMUC Research Ethics Committee. You should not proceed with any aspect of your research which involves the use of subjects/participants, or the use of data which is not in the public domain, until you have been granted Ethical Approval.

For completion by the Head of Subject / Head of Research Centre

Either

I refer this application back to the applicant for the following reason(s):

Signed _____ Date _____

Name _____ (Head of Subject / Research Centre)

Please return the form to the applicant.

Or

Please choose one of the alternatives below and delete the others.

I refer this application to the QMUC Research Ethics Committee.

I find this application acceptable and an application for Ethical Approval should now be submitted to a relevant external committee.

I grant Ethical Approval for this research.

Signed _____   Date_____

Name _____   (Head of Subject / Research Centre)

Please send one copy of this form to the applicant and one copy to Linda Graham, Secretary to the Research Ethics Committee, in Registry.

Appendix 4

Ethical Approval Letter

Julie Ferguson
Postgraduate Student
Psychology

Dawn Martin
Assistant Registrar (Quality Enhancement)
Queen Margaret University College
Clerwood Terrace
Edinburgh EH12 8TS
Direct Dial
Tel 0131 317 3211 Fax 0131 317 3248
Email: dmartin1@qmuc.ac.uk

17 April 2006

Dear Julie

Ethical Approval – The identified educational needs of patients with implantable cardioverter defibrillators

Thank you for resubmitting your application for ethical approval to the Research Ethics Committee.

The Research Ethics Committee considered your application for ethical approval for the above research project at its meeting on 12 April 2006, and I am pleased to inform you that it has granted ethical approval. For your information, the reviewer's comments on your application are enclosed. These are intended constructively and are not conditions of approval.

A standard condition of this ethical approval is that you are required to notify the Committee, in advance, of any significant proposed deviation from the original protocol. Reports to the Committee are also required once the research is underway if there are any unexpected results or events that raise questions about the safety of the research. Notification of completion of the study is also required – please find the appropriate form for this enclosed.

We would like to thank you for your co-operation and wish you well with your project.

Yours sincerely,

Dawn Martin
Secretary to the Research Ethics Committee

Appendix 5

Participant Information Sheet

Queen Margaret University
EDINBURGH

The informational Needs and Concerns of Patients with an Implantable Cardioverter Defibrillator (ICD) and their Partners

Request for Participants

1. What is the study about?

This research is to find out what concerns people with ICD's and their partners have regarding the ICD, what knowledge they have about the ICD and what information they would like to have been told before and after having the ICD inserted. This topic was identified by staff at Chest Heart and Stroke Scotland as being one that they would like investigated.

2. Who is carrying out the study?

The study is being carried out by Julie Ferguson for the award of Professional Doctorate in Health Psychology under the supervision of Dr Michele Hipwell and Dr. Heather Wilkinson.

3. What does the study involve?

The study will involve being interviewed by myself. You will be asked questions about the information and support you/your partner was given, how your life has changed since you/your partner had the ICD inserted, and how the ICD has affected you and your family.

The interview will be taped, but the tape from your interview will only be available to my Supervisor and myself. Once the interview has been transcribed, you will be sent a copy to read through and comment on and the tape will be destroyed. You will not be able to be identified from the transcription.

4. How much time will the study take?

Times will vary according to the individual but it is estimated that the interview will take no longer than 1 hour

5. Who can participate in the study?

People who have had an ICD inserted between 3 months and 2 years ago. Partners of people who have had an ICD inserted between 3 months and 2 years ago.

6. Can I withdraw from the study?

Being in this study is completely voluntary - you are not under any obligation to consent to participate and you can withdraw at any time. You are also free to withhold any information you are not happy to disclose. If you agree to take part though, it is important that you answer the questions in the interview as fully as possible.

7. Will the study benefit me?

The information you give will assist the health professionals to understand the needs and concerns of patients and help them with the development of services for people with an ICD's

What if I require further information?

If you have any questions NOW OR LATER, please contact myself, Julie Ferguson either email: jferguson@qmu.ac.uk or by phone on 0131 474 0000 (a voice activated system, please clearly state the name of the person you wish to speak to)

If you would like to speak to a member of staff at Queen Margaret University Dr. Joyce Willock (tel 0131 474 0000) is available to speak to you.

8. If I want to participate what do I do?

If you wish to participate please contact me on the above number, and we can arrange a mutually suitable time and place to conduct the interview.

Thank you for your time

Julie Ferguson

Appendix 6

Consent form

Queen Margaret University
EDINBURGH

<u>Consent form</u>

I agree to participate in this study.

I have read and understood the participant's information sheet and this consent form.

I know that all information given will remain anonymous and confidential to the researcher and her supervisor.

I have had opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study.

I understand that I have the right to withdraw from this study at any stage without giving a reason.

Name of participant: --

Signature of participant: ---

Signature of investigator: ---

Date: ---

Thank you
Julie Ferguson

Appendix 7

Interview Schedule for Patient

- Can you tell me about the circumstances surrounding your ICD (implanted defibrillator) implantation?

- Before you had your operation what information were you given about the effects and consequences of living with an ICD
    - How helpful/useful was this information

- What information were you given in hospital just after your ICD was inserted about how the ICD would affect your lifestyle
    - What format was this information
    - Were you given any leaflets or information sheets?
        - When were you given there
    - Who provided this information?

- How useful was this information
    - Did the information answer all of your questions?
    - What other questions did you have?

- Were you given any information from support groups etc
    - Can you tell me about this information?
    - How helpful was it?

- What was the most useful information that you received?

- How has your life changed since you got your ICD?
    - Were you told to expect this change?

- Have you experienced a change of mood since your ICD was inserted?
    - Can you describe this change?
    - Were you told to expect these feelings?
    - Have you had any support to deal with these feelings?

- How has your ICD affected your physical health?
    - In what way?
    - Were you told to expect these problems?
    - Have you had any support to deal with these problems

- o Were you told to expect this improvement

- How has your social life been affected by your ICD?
  - o Did you expect this change?

- How has your ICD affected your family/relationship with partner?
  - o In what way?
  - o Were given any support for this?

- Knowing what you know now what would you have liked to have been told?

- What advice would you give to someone who is about to have an ICD inserted?

- In general were you glad that you had the ICD inserted?

- Is there anything you feel I should have asked but haven't?

- Is there anything you would like to ask me?

Appendix 8

Potential questions included in interview with

partner

- ❑ Before your partner/relative had their operation what information were you given about the effects and consequences of living with an ICD?

- ❑ What information were you given just after your partner/relative's ICD was inserted about how the ICD will affect their lifestyle?
    - o What type of information were you given (leaflet, verbal etc)
    - o Who provided the information?
    - o Were you or your partner/relative given any leaflets or information sheets about the ICD?
        - ▪ When were you given these
        - ▪ How helpful was this information?

- • Knowing what you know now, what would you like to have been told?

- • Has your life changed since your partner/relative got the ICD?
    - o In what way?
    - o Did you expect this change?

- • Has your partners/relatives mood changed since their ICD was inserted?

- • Has your partner/relative had any physical problems since their ICD insertion?
    - o What were these problems?

- • Has your social life been affected by since your partner/relative had their ICD inserted?
    - o In what way?
    - o Why is this?

- • Has your partners/relatives ICD affected others in your family?
    - o In what way?

- • Has your partners ICD affected your relationship in any way?
    - o Are you able to tell me how?

- • In general are you glad your partner/relative made the decision to have the ICD inserted?
    - o Why?

ID number	
Date of interview	
Partner interviewed?	

Appendix 9

Pre interview question sheet for patients

Age _____ Years

Sex   Male ☐   Female ☐

Marital status   Single ☐

Living with partner ☐   For how long? _____

Married ☐   For how long? _____

Separated/divorced ☐

Widowed ☐

Reason for ICD insertion _____

Approximate date ICD was inserted _____

Approximate number of shocks
since ICD was inserted

Occupational
status   Employed ☐   Please state occupation _____

Unemployed ☐

On sick leave ☐

Retired ☐

Other (please
specify) ☐

For interviewer use only	
ID number	
Date of interview	

Appendix 10

Pre interview question sheet for partners

Relationship to person with ICD _____

Age _____ Years

Age of partner _____ Years

Sex   Male ☐   Female ☐

Marital Status			For how long? _____ years
	Living with partner	☐	
	Married	☐	
	Single	☐	

Occupational status			Please state occupation
	Employed	☐	_____
	Unemployed	☐	
	On sick leave	☐	
	Retired	☐	
	Other (please specify)	☐	

Appendix 11

Excerpts from Interview Transcripts

Category: Getting Back to Normal

Participant A

	Initial Coding	Focused Coding	Sub Category
A: you could be lying there or you're sitting there waiting for the next one and your heart goes bumping away 20 to the dozen Interviewer: right	"waiting for the next one" Heart racing	Anxiety – re when next shock will be	Living with uncertainty
A2: so it does, it does affect you that way so you say well if it happens again then I'll do this or that, you know this is going through your mind Interviewer: unhuh	"It does affect you" Planning what they will do if another shock happens	Planning for shock	
A2: if it happens again will I call an ambulance or will I just leave it Interviewer: uhhuh	Whether to call ambulance or not?	Planning for shock	
A2: so but eh it hasn't gone twice in a row like that, since the new battery **A:** no,	Not "gone twice in a row" again Agreeing with wife		
A2: but it does affect you, because you are worried that it will happen again	Shock affects wife also. ""worried it will happen again"		

	Initial Coding	Focused Coding	Sub Category
Interviewer: right, so there's that fear, of another shock happening **A:** well thats always there, (3.0) always there, but it does happen **A2:** There is also the fear that the machine can't cope. There is also the fear that if it does happen again, what would happen if (2.0) the machine can't cope	Confirming with A2 Fear of another shock "always there" Fear machine can't cope If it happens again [tachycardia]	Fear of shock – ICD not coping	

Participant F

	Initial Coding	Focused Coding	Sub Category
D2: And if the thing is just as spontaneous as it appears to be, then, (.) It doesn't really matter what I do it well, it will either go off, or, or not go off according to (.) **D:** How its feeling not the activity I am doing, and eh as long as I'm not doing anything dangerous at the time. Then, that may be as good as it gets. [to wife] do you want to ask, say anything **D2:** [laughs] (5.0) no, I think you're right, I think I have been eh slightly over protective earlier on, but (.) now, I think now [unintelligible] you've got to, you've got to go, like you said it happens, where it happens **D:** yeah **D2:** you know what I mean, and ehm (5.0) there's nothing you can do about it really, you've got to think well it's saving your life	Unpredictable nature of shock "Doesn't matter what I do" Emotions not activity affect heart. As long as "not doing anything dangerous" "As good as it gets" Initially overprotective Now - "happens when it happens" Accepting the inevitable – nothing you can do "its saving your life"	Unpredictability Emotions not activity Not do anything dangerous Accepting situation Initially overprotective Now accepting the inevitable Accepting the inevitable Putting a positive spin on it - ICD saving life	Living with uncertainty Living with Uncertainty Focus on the positive

Category: Feeling Informed

Participant E

	Initial Coding	Focused Coding	Sub Category
Interviewer: What were the main questions that you had? **E:** Firstly I wanted to know where it would be fitted, how long would the recovery period be, how long I would be in hospital, what could I expect. These were all the questions that I was asking when I was then that day.	Questioning – where fitted? Questioning – recovery?	Questions specific to own condition	Tailored Information
So and as I say, most of it again was finding out yourself once it was done. I don't feel, I don't feel at that time that the, let me see, the after care, the nurses were brilliant, but I don't feel the information that you received about living with it was sufficient. Looking back on it	"Finding out for yourself" Nurses 'brilliant' Now - not feeling information given was sufficient	Finding out for themselves Insufficient information given	Adequate Information

Participant F

	Initial Coding	Focused Coding	Sub Category
F: I asked lots of questions. You know what's happening now, in terms of medical treatment "what's this for, what's that for", less in terms of what happens when I get out of here. **Interviewer:** yeah **F:** (3.0) I think that was probably my approach, I I think that after two weeks in hospital you just go "I want to go home" [laughs]	"Lots of questions" Questioning – "what's happening now" Focussing on the now, not on once leave hospital	Questions specific to own condition	Tailored Information

Interviewer: So since then has your questions all been answered **F:** no **F:** so as I said I was hugely unimpressed ehm so that, I still have lots of questions erm, I think the attitude seems to be one of erm the implantation has been successful erm, the system is working fine, therefore, that's it **Interviewer:** right **F:** whereas for me, no [laughs] that's not it. That's not the end of the story the end of the story is. Why is this happening. How do I stop it happening, is a lifestyle, is it diet is at reducing stress or whatever, whatever it is as though the general component to it. Erm I want to get my licence back, I want to get my life back, because at the minute I haven't got that erm and I think that by effectively parking out and saying "You've got the thing in, its working pretty, its working fine". We'll to me that's not the answer to me. It's why is, why is it happening in the first place,	Staying in hospital "I want to go home" Questions not been answered "Hugely unimpressed" Still have questions Attitude of health professional – ICD working so "that's it" "Why is it happening" "How do I stop it happening" Getting life back Health Professional - ICD working so nothing else is needed Needing more information	Questions not answered Feeling concerns not addressed Questions specific to own condition Needing to feel informed Feeling concerns not addressed	Adequate Information Tailored information Adequate Information

Appendix 12
Participant Demographic Information

ID	Age	Gender	Marital Status	Occupational Status	Reason for ICD Insertion (*as described by participant*)	Primary or secondary prevention	Date of ICD insertion	Number of shocks	Partner Inter-viewed?	Partner ID
A	49	Male	Married	Employed	Atrial fibrillation	Secondary	2008	3	Yes	A2
B	57	Female	Married	Unemployed	Ventricular tachycardia	Secondary	2004	0	No	
C	57	Female	Married	Retired	Genetic hypertrophic cardiomyopathy	Primary	2005	0	No	
D	67	Male	Married	Retired	Hypertrophic cardiomyopathy	Primary	2006	1	Yes	D2
E	51	Female	Married	Employed	Heart failure	Primary	2007	1	No	
F	56	Male	Married	Retired	Ventricular arrhythmia	Secondary	2006	multiple	No	
G	62	Male	Living with partner	Retired	Episode of ventricular tachycardia – have coronary heart disease	Secondary	2007	1	No	
H	55	Female	Married	Retired	Arrhythmia attack	Secondary	2005	1	No	
I	57	Male	Married	Employed	Ventricular tachycardia	Secondary	2006	1	No	
J	75	Male	Married	Retired	Arrhythmia attack	Secondary	2003	6	No	
K	67	Male	Married	Retired	Arrhythmia	Secondary	2003	20+	Yes	K2
L	73	Male	Living with partner	Retired	Rapid heart rate	Secondary	2006	0	No	
M	48	Female	Married	Employed	Ventricular tachycardia	Secondary	2005	0	No	
N	71	Male	Married	Retired	Hypertrophic cardiomyopathy	Primary	2004	0	Yes	N2