Shocked: Confronting The Decision To Accept Or Decline An Implantable Cardioverter Defibrillator (ICD)

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The candidate confirms that the work submitted is her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

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For Dani,

> *‘None of us know for sure what's out there. That's why we keep looking. Keep your faith. Travel hopefully. The universe will surprise you, constantly’*
>
> (Dr Who 13th, December, 2018) xx

Abstract

Background And Aim: Primary cardiac rhythm management device (CRMD) provides potentially lifesaving treatment for people at risk of sudden cardiac death. Yet the enormity and uncertainty of benefits and harms present challenges for patient decision-making surrounding device implantation. There was limited international and no UK based research related to the process and influences affecting patient CRMD decision-making. The aim of this research was to explore ‘what influences adult patients' decision-making in accepting or declining primary prevention complex cardiac rhythm management devices?’

Research Methods And Analysis: A scoping review, followed by a four step, mixed methods, concurrent research design, with three strands was employed. Strand one involved completion of a structured questionnaire, administered to a convenient sample of 50 patients, across 4 implant sites. Strand two entailed concurrent semi-structured interviews with a purposive sample of 17 patients who had accepted, and 3 who had declined a cardiac device. A range of statistical testing was applied to the Strand 1 data using IBM SPSS statistical software v25. Framework analysis was used to analyse the Strand 2 narrative data. The data sets were merged and integrated into Strand 3.

Findings: A novel theoretical model of patient decision-making for primary CRMD was developed. Four types of decision-making emerged in response to a recommendation for CRMD. They are *Leap Of Faith*, *Reinforced Acceptance*, *Reinforced Refusal* or *Reconsideration*. Certain socio-demographic and situational factors appeared to predict and influence the type of decision-making. The level and accuracy of knowledge acquisition, information recall and informed consent characterised the alternate decision-making journeys.

Conclusion: An appreciation of the type of decision-making may inform the development of a framework of tailored information and communication to enable effective decision making, to meet specific needs and situations, to facilitate truly informed choices, and help acceptance and adjustment to life with this significant technology.

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Abbreviations

AED	Automatic External Defibrillator
AF	Atrial Fibrillation
ANOVA	Analysis Of Variance
ARVC	Arrhythmogenic Right Ventricular Cardiomyopathy
BHF	British Heart Foundation
BME	Black and Minority Ethnic
BOS	Bristol Online Survey
COMFORTID	Comparison Of Male and Female psychological Outcomes Related To Implantable cardioverter Defibrillators
C-MHLC	C Form – Multidimensional Health Locus of Control
COPE	Coping Orientation to Problems Experienced
CQC	Care Quality Commission
CRD	Centre for Review and Dissemination
CRMD	Cardiac Rhythm Management Device
CRT	Cardiac resynchronisation Therapy
CRT-D	Cardiac Resynchronisation Therapy with Defibrillation
CRT-P	Cardiac Resynchronisation Therapy with Pacing Only
DA	Decision Aid
DCM	Dilated Cardiomyopathy
DCP	Decisional Control Preferences
DCT	Decisional Conflict Theory
Diff Con	Differentiation and Consolidation Theory
DRS	Decisional Regret Scale

EP	Electrophysiologist
EPS	Electrophysiological Studies
GDPR	General Data Protection Regulation
HAD	Hospital Anxiety and Depression
HCM	Hypertrophic Cardiomyopathy
HF	Heart Failure
HIV	Human Immunodeficiency Virus
HL	Health Literacy
HLS-EU	Health Literacy Survey - European
HRA	Health Research Authority
HRQL	Health Related Quality of Life
HSM	Heuristic Systematic Processing Model
ICC	Inherited Cardiac Conditions
ICD	Implantable Cardioverter Defibrillator
ICD-DAS	ICD Decision Analysis Scale
IDCM	Ischaemic Dilated Cardiomyopathy
IHD	Ischaemic Heart Disease
LBBB	Left Bundle Branch Block
LV	Left Ventricle
LVEF	Left Ventricular Ejection Fraction
MI	Myocardial Infarction
MBSS	Miller Behavioural Style Scale
MM	Mixed Methods
MMAT	Mixed Methods Appraisal Tool
MMR	Mixed Methods Research
MOS-SF	Medical Outcomes Survey – Short Form
NHS	National Health Service
NIDCM	Non-Ischaemic Dilated Cardiomyopathy
NICE	National Institute for Clinical Excellence

NSVT	Non Sustained Ventricular Tachycardia
NVS-UK	Newest Vital Sign - UK
NVQ	National Vocational Qualification
NYHA	New York Heart Association
ODSF	Ottawa Decision Support Framework
OHS	Open Heart Surgery
PCI	Percutaneous Coronary Intervention
PI	Primary Investigator
PIC	Participant Identification Centre
PIN	Personal Identification Number
PIS	Patient Information Sheet
PM	Pacemaker
POMS	Profile Of Mood State
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR	PRISMA Extension for Scoping Reviews
R&D	Research And Development
RBBB	Right Bundle Branch Block
REALM	Rapid Estimate of Adult Literacy in Medicine
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
SAHL	Short Assessment of Health Literacy
SCA	Sudden Cardiac Arrest
SCD	Sudden Cardiac Death
SDM	Shared Decision-making
S-ICD	Subcutaneous Implantable Cardioverter Defibrillator
SVT	Supraventricular Tachycardia
TMSI	Threatening Medical Situations Inventory
TOFHLA	Test Of Functional Health Literacy in Adults

UK	United Kingdom
USA	United States of America
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
WHO	World Health Organisation

Chapter 1

Introduction And Background

1.1 Introduction

The focus of this thesis is patient decision-making for an implantable cardioverter-defibrillator (ICD). The ICD was pioneered in the 1970's by Dr Michel Mirowski, a Polish born cardiologist working at the Sinai Hospital, Baltimore, USA. Dr Mirowski was one of the first clinicians to recognise the scope of sudden cardiac death (SCD), and raise awareness among colleagues with his efforts to develop an alternative to anti-arrhythmic drugs for the treatment of life threatening ventricular arrhythmias (Kastor, 1989). Despite scepticism and criticism by cardiologists at the time, the first prototype ICD was implanted and tested in a dog in 1975 (Dyell et al., 2010). In 1980, the first generation, secondary prevention ICD was successfully implanted in a 57 year old female with frequent episodes of ventricular fibrillation (VF) (Mirowski et al., 1980). The development of the ICD revolutionised the treatment and subsequently, the prevention of sudden cardiac arrest (SCA). In 1990, the first second generation ICD was implanted abdominally in a male patient in Leeds. It was large, heavy, relatively unsophisticated but successfully treated his ventricular arrhythmias. Since then, a range of complex cardiac rhythm management devices (CRMD) have been introduced into cardiology practice.

From a clinical background in cardiology, the personal motivation for undertaking this thesis is founded upon a longstanding interest in the general well-being of recipients of complex CRMD. Rapid technological advances in device sophistication, a UK drive to increase implant rates to match EU and US targets, and detailed insight of the psychosocial implications of implantation derived from undertaking the COMFORTID study (Marshall et al., 2012), served to focus attention upon understanding the complex phenomena surrounding the process and influences of device decision-making. A deeper understanding of the context, process and individual experience would satisfy a gap in knowledge of the pre-implant patient journey. Furthermore, advancing knowledge of potential differences among patients may influence the development of interventions to positively affect the pre-implant patient experience. This chapter introduces the enormity of the problem, reviews what is known about patient treatment decision-making in the context of decision theory and ends with a summary of the rationale for the research question posed for this PhD thesis. The final section of this chapter provides an outline of the chapters which form this thesis.

1.2 The Enormity Of The Problem

SCD affects approximately 50 to 70,000 people in the UK annually (NHS, 2013). It is estimated that 75 to 80% of SCD's in England and Wales in 2010, resulted from ventricular arrhythmia, most often associated with underlying heart disease or inherited conditions (Priori et al., 2015; NICE, 2014). Despite increased availability and awareness of the automatic external defibrillator (AED), survival from out of hospital SCA has improved in recent years but remains low at approximately 12 to 32% (Fothergill et al., 2013). Survivors are at high risk from SCD within 2 years however those who receive appropriate treatment have a 69 to 100% chance of survival at 5 years (NICE, 2014). Furthermore, in a significant number of cases, SCD occurs with no previous arrhythmia warning, warranting careful consideration of patients who are at risk of SCD despite the absence of an event and therefore require primary preventative measures (Priori et al., 2015; Fishman et al., 2010).

Cardiac causes include ischaemic heart disease (IHD), acute myocardial infarction (MI), cardiomyopathies, valve disease, congenital heart defects, myocarditis and electrical conduction disorders (Priori et al., 2015). Heart failure, caused by structural or functional cardiac disorders is a chronic condition which affects 140 per 100,000 men and 120 per 100,000 women predominantly over the age of 50 years in the UK (NICE, 2014). NICE estimate that in England and Wales, approximately 900,000 people have left, right or biventricular heart failure of which more than 50% have systolic dysfunction (2014). Clinically, heart failure is classified according to the impact upon functional capacity using the New York Heart Association (NYHA) system of increasing severity from class 1 to IV (NICE, 2014). The prognosis with heart failure is poor with approximately 40% dying within 1 year of diagnosis (Jones et al., 2017). Those with severe heart failure (NYHA IV) are most likely to die from pump failure where as those with mild to moderate symptoms ($\leq$ NYHS III) are at greater risk of arrhythmic death (McMurray et al., 2012). Specific interventions such as revascularisation, radiofrequency ablation, surgical repair, transplant and medical management aim to improve mortality and morbidity. However, some people remain at higher than average risk of SCD and therefore additional measures such as anti-arrhythmia drug therapy or complex cardiac rhythm management devices (CRMD) will be recommended (NICE, 2014).

1.2.1 The Benefit Of CRMD Therapy

Unequivocal evidence of the benefits of primary and secondary ICD implantation in appropriately selected people at risk of SCD is now well established (Epstein, A. et al., 2013). Meta-analysis of large randomised controlled trials (ĂVID, CIDS, CASH) has firmly established the mortality benefit of CRMD such as implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy (CRT) over conventional drug therapy, in a targeted but growing population of people who have survived (secondary device) or are at substantial risk (primary prevention) of SCA (Smith, T. et al., 2013; Goldenberg et al., 2010; Bardy et al., 2005; Moss et al., 2002; Connolly et al., 2000).

Three devices of increasing complexity are currently implanted. The subcutaneous implantable cardioverter defibrillator (S-ICD) requires positioning of a pulse generator in the subcutaneous tissue at the 6th rib left mid axillary region, attached to a vertical lead situated parallel to the left sternal border (Rowley and Gold, 2012). This device is capable of providing highly sensitive rhythm discrimination algorithms and defibrillation in response to rapid ventricular arrhythmias only. The traditional ICD is reliant upon a smaller subcostal pulse generator and multi chamber trans-venous lead system (Albakri, 2019). This ICD includes multi programmable features including adaptive rate overdrive pacing, low energy cardioversion for slower, haemodynamically stable ventricular tachycardia (VT), or defibrillation for high rate VT or ventricular fibrillation, with bradycardia support pacing. NICE (2014) recommend ICD for prevention of life threatening arrhythmia following survival of ventricular tachycardia (VT) or ventricular fibrillation (VF) cardiac arrest, or evidence of sustained VT with syncope or significant haemodynamic compromise, or without syncope ± ischaemic heart disease, and reduced left ventricular ejection fraction (LVEF) of < 35% and symptoms no worse than New York Heart Association (NYHA) class III (Table 1.1).

Table 1-1 Clinical Indications For Cardiac Rhythm Management Device

QRS Interval	NYHA Class I	NYHA Class II	NYHA Class III	NYHA Class IV
<120 ms	ICD if high risk of sudden cardiac death			ICD & CRT not clinically indicated
120 – 149 ms without LBBB	ICD	ICD	ICD	CRT-P
120 – 149 ms with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P
≥150 ms ± LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P

ms = milliseconds. LBBB = left bundle branch block. NYHA = New York Heart Association. CRT-P = CRT and pacing. CRT-D = CRT and defibrillator. (NICE, 2014)

Devices are also offered to people at high risk of sudden death due to familial cardiac conditions such as long QT syndrome, hypertrophic cardiomyopathy (HCM), Brugada syndrome, arrhythmogenic right ventricular cardiomyopathy (ARVC) or following surgical repair of congenital heart disease, such as Fallot's tetralogy (NICE, 2014).

CRT-P primarily provides synchronised bi-ventricular pacing to improve overall cardiac output in heart failure, thus offering survival and symptomatic benefit (Goldenberg et al., 2014; Cleland et al., 2013; Bristow et al., 2004). However, as ventricular arrhythmia is the most common cause of death with mild to moderate heart failure some patients require a combination of bi-ventricular pacing and ICD functionality, denoted as CRT-D (NICE, 2014). ICD and CRT-D devices provide the clinical focus for this project and will be referred to either independently or as CRMD.

1.2.2 Potential Risks And Disadvantages Of CRMD Therapy

Despite the evident survival benefit, CRMD implantation is associated with significant potential physical complications and well documented patient and partner psychosocial concerns (Dunbar et al., 2012). Post procedural complications include access related haemo-pneumothorax (1.1%), haematoma or thrombosis (1.2%), lead displacement and malfunction (5.2%), box failure or erosion and infection (1.5%) (van der Heijden et al., 2015; Ezzat et al., 2015). Many aspects of life may be adversely affected including driving (Johansson and Stromberg, 2010), sexual relations (Steinke et al., 2013), sleep (Berg et al., 2012), body image (especially young women) (Marshall et al., 2012; Vazquez et al., 2008) and sports participation (Zeigler and Nelms, 2009). For some device recipients the experience manifests as prolonged and persistent psychological problems, including anxiety (8–63%), depression (5–41%) (Lang et al., 2014; Hoogwegt et al., 2012; Magyar-Russell et al., 2011; Dunbar et al., 2009; Sears and Conti, 2006), emotional lability and adjustment disorders, adversely affecting perceived quality of life (QOL) (Mauro, 2008; Thomas et al., 2006). Furthermore, the occurrence of ICD shocks, particularly ‘electric storm’ and ICD malfunction causing inappropriate shocks are associated with increased psychological distress for recipients and families, worse outcomes and increased health care costs (van der Heijden et al., 2015; van Rees et al., 2011; Pedersen et al., 2010; Daubert et al., 2008). The intensity of successive shocks, unpredictability, multiplicity, lack of warning, enforced avoidance of certain activities, lifestyle alterations and feelings of uncertainty and dependence upon an electronic device were persistent complaints (Eckert and Jones, 2002; Dunbar et al., 1999; Dougherty, 1995). Though levels of distress vary, some patients with recent tachyarrhythmia’s display anticipatory shock anxiety (Morken et al., 2014) and in severe cases post-traumatic stress disorder associated with shock therapy, and pre-implant distress has been documented (Versteeg et al., 2011; Sears et al., 2011).

A standard ICD does not affect the patients underlying cardiovascular condition or symptoms, though bradycardia pacing may support an increase in pharmacological support. Whereas, restoration of ventricular synchrony with CRT may improve heart failure symptoms and health related quality of life (HRQL) (Goldenberg et al., 2014). The risk of shock related distress may equally apply, and patients who may derive no direct benefit from device therapy are still exposed to procedural and device-related complications. Selection for CRMD is not age restricted (Kusumoto et al., 2018). Thus, the extended period of implantation subjects younger recipients to an increasing potential for complications. Alternatively, older adults may have to contend with multiple, co-existent illness and competing co-morbidities. This may confer limits to the potential survival advantage of CRMD (Sandhu et al., 2019). Furthermore, CRMD implantation requires regular routine follow up to monitor device activity history, make necessary alterations to sensing parameters, therapeutic settings and measure battery life. Battery or device replacement necessitates further surgical intervention with its inherent risks (Kramer et al., 2012). Lastly, CRMD obliges pre-emptive discussion of device deactivation at the end of life, particularly among older adults (Goldstein et al., 2014).

CRMD therapy has been shown to prolong life however, the extent to which mortality benefit outweighs potential adverse effects on morbidity, quality of life and the mode of death is less clear. The enormity and uncertainty of both benefits and harms present challenges for the decision-making process surrounding CRMD implantation for patients. The fundamental right to be involved in healthcare decision-making and give informed consent is integral to the NHS constitution and NICE guidance (Department Of Health, 2015). Irrespective of the indication for CRMD therapy, a paternalistic recommendation based upon the eligibility criteria outlined in clinical practice guidelines, without acknowledgement of patient preferences threatens individual autonomy and the ethos of informed consent (Joyce et al., 2013). It is therefore imperative that decision-making be informed and consistent with patient preferences (Green et al., 2016). The goal of effective decision-making is to ensure that patients are sufficiently prepared to reach an informed decision in a way that reduces the risk of cognitive dissonance, decisional conflict and regret and enhances decisional satisfaction (Orom et al., 2016). The degree of satisfaction with the decision to accept or decline CRMD implantation is complex, may affect the quality of the immediate treatment phase and influence the individuals overall acceptance, psychosocial adjustment and long term outcomes with or without the device, and therefore warrants further investigation (Dunbar et al., 2012). The professional mandate to promote patient involvement in decision-making, uphold the right to informed choice and the potential to impact upon patient outcomes, formed the driving force for this thesis.

1.3 Patient Decision-making

> '*Patient decision-making refers to an ongoing process comprising complex cognitive, perceptual, affective, behavioural and relational components by which individuals select an acceptable solution or a salient alternative concerning a health-related issue, influenced by interactions among individual and contextual factors, culminating in decisional consequences and post-decisional appraisal'* p919 adapted from Pierce and Hicks (2001) cited in Strohschein et al. (2011).

Background reading revealed a substantial amount of literature about patient decision-making and great divergence in subject specific focus. 'Clinical' or 'medical' decision-making, macro and micro healthcare policy decision-making and 'shared decision-making' were frequently intertwined, and yet essentially refer to different phenomena. Studies concerned with particular patient groups often focused upon chronic illness, for example rheumatology, orthopaedic, respiratory, HIV infection or inflammatory bowel disorders and covered issues related to health screening, prevention, alternative therapies, beginning or end of life matters and capacity issues. Studies concerned with patients making complex treatment decisions in the context of severe, life threatening illness, focused upon treatment choices of women with breast cancer, patients with colorectal cancer, and men with prostate cancer. Also cardiac specific intervention such as angiography or primary coronary intervention (PCI), or cardiovascular disease such as carotid endarterectomy, stroke and hypertension. There was minimal focus upon CRMD therapy.

The literature related to patients decision-making in relation to treatment for life threatening cancer revealed an extensive coverage of issues addressing a range of theoretical perspectives. These included patients actual decision-making experience, that is the process by which individuals internalise and execute decision thoughts, collective or relational approaches to decision-making such as preference for particular participatory styles, demographic influences, interventions such as decision aids or the development and validation of outcome measures. Some studies lacked clear reference to underpinning theory while others appeared to explore multiple facets leading to an apparent blurring of conceptual boundaries which serves to highlight the complexity of the concept. Several decision-making theories attempt to explain how patients approach treatment decisions.

1.3.1 How Do Patients Approach Treatment Decisions?

Decision-making theories, categorised according to normative, descriptive and prescriptive approaches, attempt to explain how patients make the final treatment choice (Thompson and Dowding, 2009). Normative approaches which assume rationality (analytic processing), leading to an optimal decision are considered to be how individuals should make decisions under conditions of uncertainty (Appendix A) (Thompson and Dowding, 2009). They rely upon the systematic assessment and numerical quantification of the utility of outcomes and probability of outcomes occurring, of all possible alternatives and their consequences, in order to match the options to a known set of goals, and therefore determine the expected value of each choice (Shafir et al., 1992). The rational decision-maker chooses the option which yields the highest expected utility or value and is most likely to achieve their desired goals. Non-analytic factors such as heuristics, emotions or intuition are thought to disrupt effective decision-making. However, studies concerned with the quality of treatment decision-making which revolved around the premise of analytic processing assumptions uncovered exceptions to logical, deliberative decision-making (Singer et al., 2003; Pierce, 1993). Pierce (1993) and Lam et al. (2005) found that women with breast cancer who relied upon rational approaches did not always reach the best choice and were more likely to experience greater psychological distress, uncertainty, anticipated regret and dissatisfaction than women who used alternative decision styles.

It is now widely accepted that in the context of difficult treatment decision-making, humans are rarely purely rational but display ‘limited’ or ‘bounded rationality’ (Gigerenzer and Goldstein, 1996; Simon, 1983). This is derived from limited knowledge of complex treatment options, high degrees of uncertainty, relatively short time frames and health related cognitive impairment. Decision-making is hampered by ‘limited instrumental rationality’ arising from problems with attention, memory, comprehension and communication (Epstein, R., 2013; Thompson and Dowding, 2009). Under such circumstances, it is acknowledged that rational, calculative decision-making is not attainable. Therefore, not all individuals will necessarily trade the benefits and risks but may minimise cognitive effort and time, settling for a suboptimal outcome known as ‘satisficing’. That is, the human tendency to make choices which meet a minimum criterion and are ‘good enough’ rather than optimal choices (Thompson and Dowding, 2009; Gigerenzer and Goldstein, 1996). An optimal decision is not possible, therefore heuristic methods are employed to speed up the process of decision-making to arrive at the best possible outcome. The term ‘heuristic’ describes a general decision-making strategy which is based upon limited information, and reliance upon mental short cuts employed to reduce cognitive burden associated with decision-making (Tversky and

Kahneman, 1974). It may lead to decision-making which is considered to be less thorough (Tversky and Kahneman, 1974). Proponents of normative models of decision-making accept the inclusion of heuristic thinking strategies. However, they are generally viewed as errors and biases derived from an individual’s cognitive limitations and are said to result in sub-optimal decision-making (Broadstock and Michie, 2000). Therefore, the aim of effective communication is to debunk heuristic biases in order to achieve an optimal decision, through rational, analytic deliberation. Thus, while expected utility theory has been used to defend macro resource allocation and meso-level policy and guideline development (Elwyn et al., 2011; Stiggelbout and de Haes, 2001), application of normative principles to treatment decision-making in the context of serious, life threatening illness is limited, less well known and considered to be too unreliable to apply to individual (micro) patient decision-making (Slot and Berge, 2009; Singer et al., 2003).

The focus of treatment decision theory has subsequently progressed from normative, rational approaches based upon expected utility to descriptive theories which acknowledge bounded rationality (Simon, 1983; Simon, 1967; Simon, 1956). In contrast to normative approaches, descriptive, naturalistic decision theories appear to be more evident and pertinent to the study of complex treatment decisions in the real world. Naturalistic theory considers decision-making in the context of uncertainty and bounded rationality.

1.3.2 Individual Approaches To Decision-making

Appendix B provides a summary of the key decision theories that attempt to explain individual decision-making. Several models such as the Decisional Conflict Theory (DCT) Model (Janis and Mann, 1977; Flynn et al., 2006; Pinquart et al., 2004); Fuzzy Trace Theory (Reyna and Brainerd, 1991); Differentiation & Consolidation (Diff Con) Theory (Svenson, 1992) and the Decisional Model of Stress and Coping (Balneaves and Long, 1999; Folkman and Lazarus, 1985), featured in the patient treatment decision-making literature in an attempt to explain choice behaviours in the dynamic context of personal and situational factors. According to Decisional Conflict Theory (DCT), an increasing awareness of positive and negative outcomes may create decisional conflict, which in turn increases psychological stress, and that influences decision-making behaviours (Janis and Mann, 1985; Janis and Mann, 1977). Studies that focused upon the impact of decisional conflict leading to increased stress and eliciting one of four maladaptive (un-conflicted adherence, un-conflicted change, defensive avoidance, hypervigilance), or an adaptive (vigilance) coping pattern of decision-making dominated the early literature (Balneaves and Long, 1999; Hollen, 1994; White et al., 1994; Baradell and Klein, 1993; Terry, 1992; Janis and Mann, 1977).

Attention then turned to individual decision-making, that is the process by which individuals internalise, judge and execute decision thoughts. This involves a combination of systematic and non-systematic information processing such as heuristics (cognitive shortcuts) (Kahneman, 2011; Gigerenzer and Todd, 1999; Chen, S. and Chaiken, 1999; Kahneman and Tversky, 1996; Gigerenzer and Goldstein, 1996; Tversky and Kahneman, 1974). This two system theory acknowledges a dual process of information gathering using parallel, interactive, cognitive systems (Kahneman, 2011; Chen, S. and Chaiken, 1999). The ‘experiential system 1’ involves processing information in a rapid, automatic, intuitive, associative, affective, non-conscious and effortless manner, whereby only the end result is noted in consciousness (Epstein, S., 1991). Kahneman (2011) coined the term ‘thinking fast’ to describe the activation of the ‘experiential system 1’. He ascribes this to the automatic, unconscious operation of ‘system 1’, which has some basis in Spinoza’s theory of believing and unbelieving (Gilbert et al., 1993). That is, understanding is inextricably linked to believing information and this occurs on initial exposure to it. It is often emotionally charged and thus difficult to control or modify. It is associated with heuristic information processing, that is a reliance upon information that readily comes to mind. Heuristic methods focus upon relatively quick, affective, effortless information processing based upon prior knowledge, experience of self and others, expectancies, schemas and stereotypes from which a set of ‘rules of thumb’ are derived (Steginga and Occhipinti, 2004; Epstein, S., 1991; Chaiken, 1980). Heuristic thinking is acknowledged as an integral aspect of patient decision-making in situations where a high degree of uncertainty and ambiguity prevails (Marewski and Gigerenzer, 2012; Vaugh, 1999).

The ‘expert opinion heuristic’ has been described as a non-systematic decision-making strategy grounded in the view that “experts can be trusted” and associated with deferral of decision-making responsibility to the physician (Steginga and Occhipinti, 2004; Steginga and Occhipinti, 2002; Chaiken et al., 1989). Kahneman and Tversky (1996) described the ‘availability heuristic’ as referral to an instance affecting a decision which readily comes to mind, based upon personal past experiences or that of others which may be positive or negative. Thus, ‘heuristic cues must be cognitively available, accessible and applicable to the decision context’ for heuristic processing to occur (Steginga & Occhipinti 2004 p573).

Investigating the internal thought processes employed by an individual to reach a decision is not without difficulty and indeed criticism (Bellur and Sundar, 2014; Hamm, 2004). Hamm (2004) argued that measuring the instances of self-reported references to requests for the expert's opinion, and deferral to a doctor in a survey or transcript as evidence of expert-opinion heuristics was tenuous at best. Similarly Hamm (2004) criticised the suggestion by Steginga and Occhipinti (2004) that reference to a positive or negative anecdote was evidence of a decision based upon availability heuristics. Hamm (2004) proposed an alternative strategy to assess the use of a heuristic strategy through analysis of the outcome. However, this would rely upon alternative methods of framing the expert's advice in terms of positive or negative outcomes to determine the extent to which it affected the decision. Capturing and measuring the impact of heuristics upon decision-making in this way presents a number of ethical concerns particularly in relation to beneficence and coercion. Furthermore, such criticism appears to be solitary. Therefore, in the absence of an alternative workable solution, reliance upon verbal reports from patients as evidence of heuristic processing, continued to dominate studies that seek to explore and explain what influences decision-making.

Proponents argue that automatic processing strategies may be adaptive, resourceful and effective as they rely upon fewer sources of information, and information that supports beliefs are accepted and therefore further sourcing is considered to be a waste of cognitive time and effort (Broadstock and Michie, 2000). Therefore, descriptive theory accepts the reality of automatic, fast information processing. For some people fast heuristic thinking will be supplemented by slower, systematic information gathering and deliberation. The 'rational system 2' is slow, deliberate, sequential, conscious and effortful thinking (Kahneman, 2011; Epstein, S., 1991). Systematic approaches focus upon purposeful and analytic information gathering and examination of thoughts and feelings to arrive at a decision (Epstein, S., 1991; Chaiken, 1980). 'Thinking slow' occurs when intuitive thinking triggers system 2 'systematic information gathering and processing' (Kahneman, 2011).

An increasing understanding of the physiological basis has strengthened confidence in the assumptions of dual process theory. Neurophysiological studies have identified distinct cerebral regions which are responsible for the control of the emotion and cognition systems (Hsu et al., 2005). The amygdala region controls 'fast' intuitive, emotion based responses and the prefrontal cortex is concerned with 'slow' deliberative cognition (Hsu et al., 2005). Systematic and non-systematic, heuristic decision approaches are not necessarily mutually exclusive but may operate in synchrony or in conflict. Although not fully understood, both systems appear to cooperate interdependently to enhance one another, or independently to suppress the response of the other (Luo and Yu, 2015; Kahneman, 2011; Epstein, S., 1991). The most effective decisions are thought to arise when a combination of the two modes of information processing enable decision-makers to think and feel there way to an appropriate decision (Peters et al., 2007; Damasio, 1994). However, dual process theory also recognises the potential antagonism between intuitively produced, emotionally laden judgement and decisions based upon rational, deliberative thinking. A reduction in one, such as deliberative cognitive capacity may lead to an increased emphasis upon affective reasoning (Epstein, S., 1994). Therefore, in certain contexts emotion may override cognition and influence decision-making. This may be mediated by emotional exaggeration or cognitive reduction (Luo and Yu, 2015).

In terms of healthcare, the reputation and opinion of the physician as a credible source and / or simultaneous heuristic thinking may also influence or bias systematic processing particularly when faced with ambiguous information and so affect decisions made (Katz, S. and Hawley, 2007; Lam et al., 2005; Steginga and Occhipinti, 2004; Kahneman and Tversky, 1996). Studies have found that the degree of individual engagement with systematic and heuristic information processing appears to be highly variable and influenced by a range of factors (Katz, S. and Hawley, 2007; Lam et al., 2005; Steginga and Occhipinti, 2004) deserving further enquiry. The Heuristic-Systematic Processing Model (HSM) frames the role of non-systematic, heuristic and systematic information processing in decision-making, and provides a theoretical framework for the examination of individual patient decision-making (Chen, S. and Chaiken, 1999).

1.3.3 Collective Approaches To Decision-making

Participatory decision-making has been conceptualised according to several models revolving around the level of control an individual has over decision-making, ranging from ‘passive’ paternalistic physician control, to ‘active’ informed patient control or shared involvement in information exchange, deliberation and final choice between physician, patient and significant others (Mead et al., 2013; Makoul and Clayman, 2006; Charles et al., 1999). Appendix C summarises collective, participatory decision-making theory. Shared decision-making (SDM) is widely advocated as the gold standard in the literature (Stacey et al., 2014; Mead et al., 2013; Stiggelbout et al., 2012; Department Of Health, 2010a), yet while most patients appear to prefer a joint approach (Chewning et al., 2012), a significant minority favour a passive style and others a more active approach (Singh, J. et al., 2010; Hubbard et al., 2008; Say et al., 2006; Kiesler and Auerbach, 2006; Gaston and Mitchell, 2005). A connection between achieving the desired level of involvement, being informed and decisional satisfaction has been reported (Brown et al., 2012; Martinez, L. et al., 2009; Krones et al., 2008; Edwards, Adrian and Elwyn, 2006; Kiesler and Auerbach, 2006), yet discordance between desired and actual decisional control appears to be prevalent (Brom et al., 2014; Flierler et al., 2013; Brown et al., 2012; Burton et al., 2010; Singh, J. et al., 2010; Vogel et al., 2009; Hubbard et al., 2008).

More recent literature focused attention upon the distinction and interplay between individual and collective, participatory aspects of treatment decision-making (Epstein, R., 2013). Epstein, R. (2013) devised the term ‘whole mind’ to refer to the fast and slow thought processes and actions of the individual. He defined ‘shared mind’ as the collective communication among patient, expert and significant others, which seeks to assimilate and incorporate contextual information with patient values and preferences, in order to reach an acceptable if imperfect decision (Epstein, R., 2013). Thus, the concept of whole mind : shared mind encapsulates the approach to decision-making.

1.3.4 Influences Affecting Decision-making

Several reviews have cited various factors as potential influences upon the internal and collective processes of patient decision-making, such as demographics, health status, previous experience of illness and healthcare, preference for involvement and relationship with healthcare professionals (Wroe et al., 2013; Politi et al., 2013; Chung et al., 2012; Ernst et al., 2011; Singh, J. et al., 2010; Hubbard et al., 2008; Rodriguez et al., 2008; Cox et al., 2006; Kiesler and Auerbach, 2006; Say et al., 2006; Gaston and Mitchell, 2005). The impact of age, gender, cultural background, educational level, marital, socio-economic and health status upon preference for participation was inconclusive (Hubbard et al., 2008). Yet being younger, well-educated and female was associated with a greater desire to participate in decision-making in several studies (Chung et al., 2012; Deber et al., 2007; Flynn et al., 2006; Gaston and Mitchell, 2005; Janz et al., 2004; Benbassat et al., 1998). Therefore, socio-demographic influence upon patent decision-making remains unclear.

The impact of life threatening illness upon anxiety and depression is well established (Petrie et al., 2007). Whether or not an individual has experienced SCD, pre ICD implant preparation is likely to include exposure to a battery of invasive investigations such as electrophysiological studies (EPS), pharmacological trials, drug intolerance or clinical ineffectiveness, deteriorating symptoms and interventions that may further exacerbate negative psychological feelings including anxiety and depression (Hallas et al., 2010; James, 1997; Burke, 1996). Studies dating back to the 1980’s have demonstrated that anxiety significantly compromised decision-making and informed consent (Hartley and Phelps, 2012; Berry, D. et al., 2006). However, little is known regarding the influence of anxiety and depression upon patient decision-making preferences (Zeliadt et al., 2006).

1.3.5 Decisional Outcomes

The purpose of effective decision-making is to ensure that patients are sufficiently prepared to reach an informed decision, in a way that minimises decisional conflict and regret and enhances decisional satisfaction. However, regardless of the level of participation in decision-making, widespread misunderstanding and dissatisfaction with the amount of information received appeared to be common in the literature (O’Leary et al., 2007; Cox et al., 2006; Fagerlin et al., 2006; Kiesler and Auerbach, 2006; Gaston and Mitchell, 2005). In response there has been some interest in the development and validation of interventions such as patient or physician decision aids to improve information recall (Stacey et al., 2014). To date, evidence of the efficacy and expediency of using decision aids in practice remains elusive. Finally, various decisional outcome measures, including satisfaction and regret also featured in the literature (Budden et al., 2014; Stalmeier et al., 2005; Brehaut et al., 2003; Degner et al., 1997b). Studies generally suggest that involvement in decision-making results in more decisional satisfaction.

1.4 Summary Of Background Literature

In recent years much attention has been placed on meeting the specific physical and psychosocial support needs of CRMD recipients through the establishment of specific nursing roles and interventions (Dunbar et al., 2012). This includes supporting individuals pre and post CRMD implantation. Much of the recent research interest has focused upon the patients bio-psycho-social outcomes post CRMD implantation. There is a dearth of available literature regarding patient decision-making prior to CRMD implantation. Yet a wealth of knowledge related to patient cancer treatment decision-making exists. Given the context of serious, sudden life threatening cardiac arrhythmia, characterised by high degrees of uncertainty, and the uniqueness of complex cardiac device therapy, it was not known whether findings from the broader literature could be applied to patients making decisions regarding CRMD implantation. In order to meet the specific needs of patients pre-implantation, a better understanding of the way patients approach the decision to accept or decline CRMD is required. This may inform the development of specific targeted support strategies to meet individual needs. This formed the crux for further inquiry. A crucial requirement for any treatment is that the patient is sufficiently cognisant of the facts to make an informed choice and give consent (CareQualityCommission., 2018; Montgomery and Montgomery, 2016). Information, comprehension, capacity and freedom from coercion are pre-requisites for informed consent. Therefore, another important aspect of this thesis was to explore the extent to which patients were exposed to and engaged with information and whether this translated into an informed decision and consent. Furthermore, thus far the literature had revealed little to identify what influences patients decisions to accept or reject CRMD. This apparent gap in knowledge provided the rationale and overarching research question for this PhD study.

1.5 The Research Question

The overarching research question which directed this thesis was;

> **‘What influences adult patients' decision-making in accepting or declining primary prevention complex cardiac rhythm management devices (CRMD)?’**

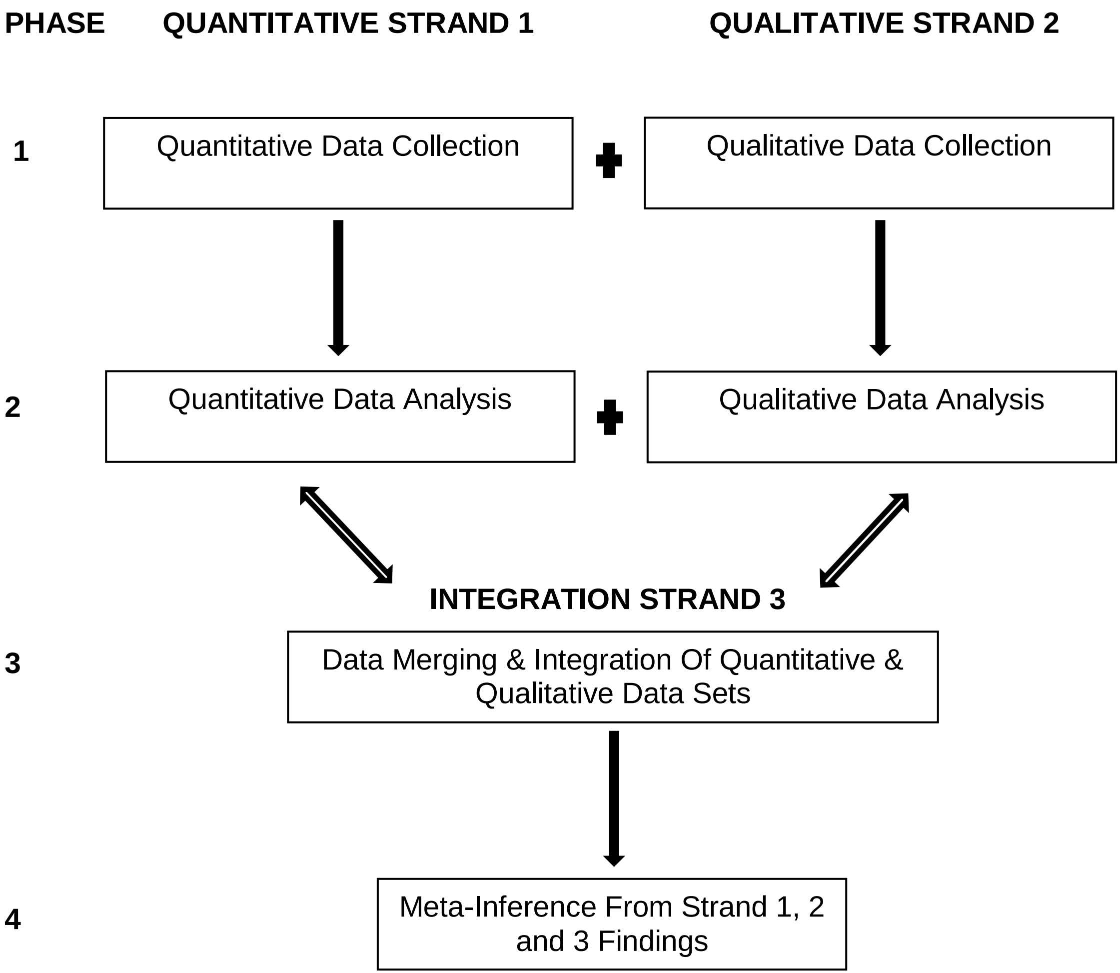
Three broad study aims were proposed to facilitate the design of the study;

Aim 1: To determine whether an association exists between existing socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret

Aim 2: To develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed

Aim 3: To examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

To address the overarching question and aims, a multi-strand, concurrent, parallel mixed methods design involving four progressive phases of research inquiry was developed and completed (Figure 1.1).



Key:

✚ denotes concurrence

⟺ denotes data mixing (Creswell, 2014; Creswell and Plano-Clark, 2011; Morse, 2003)

Figure 1-1 The Proposed Structure For The Empirical Inquiry

1.6 Overview Of Thesis

This thesis is divided in to 7 chapters. Chapter 2 provides a scoping review to discover what is known in the literature, about the way in which adult (>16 years) patients make decisions regarding implantation of complex cardiac rhythm management devices (CRMD). Chapter 3 discusses the research aims, the development of a conceptual map and research objectives emerging from the scoping review to direct the research. The rationale for selecting a mixed methods approach for this project is discussed. Chapter 4 presents the research methods and findings of the first strand of empirical research designed to achieve research aims 1 and 3. The purpose of Strand 1 was to examine potential associations and relationships among a range of variables and determine the extent to which they may or may not influence decision-making. Chapter 5 is concerned with the research methods and findings employed to undertake the second strand of empirical research. The purpose of Strand 2 was to examine, consider and construe the ideas, thoughts and feelings from the patients' perspective to gain further insight in to the subjective, contemplative perception of decision-making. It was driven by research aims 2 and 3. Chapter 6 provides a reflective analysis of the rationale and process of, merging and integration of the data sets from Strand 1 and 2 into Strand 3. The results of data integration and interpretation and the development of a theoretical model of patient decision-making for CRMD are presented. Chapter 7 provides a detailed discussion of the cumulative findings from Strand 1, 2 and 3 of this thesis. It aims to position the study findings and proposed theoretical model within the context of contemporary literature and practice. Reflections upon the research process and outcomes are considered. Implications for practice, recommendations for future research and a concluding summary are included.

Chapter 2
Literature Scoping Review

2.1 The Aim

In view of the limited reference to cardiac device therapy in the initial literature search it was evident that a broader scoping exercise would be necessary to reveal what is known about patient decision-making regarding CRMD implantation. The scoping review, initially described by Arksey and O'Malley (2005), further developed by Daudt et al. (2013) was defined as;

> '*a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence and gaps in research related to a defined area or field by systematically searching, selecting and synthesising existing knowledge'* p1294 (Colquhoun et al., 2014).

The purpose of this scoping review was to explore the extent, range and nature (breadth) of available knowledge related to decision-making among cardiac patients contemplating implantation of cardiac rhythm management devices (CRMD), identify gaps in the existing literature, and establish any key areas for further study (Tricco et al., 2018; Daudt et al., 2013; Levac et al., 2010; Arksey and O'Malley, 2005). The range and variability of study designs emerging from the preliminary background literature review was more suited to a scoping rather than systematic review. A systematic review emphasises a well-defined research question and often limits the literature to experimental study designs. In contrast, a scoping review addresses a broader question and selection criteria, encompasses various study designs and extracts detailed information for thematic rather than statistical analysis in an effort to contextualise the findings (Arksey and O'Malley, 2005). This was deemed to be more appropriate for this study. The scoping review was conducted in an equally systematic, rigorous and transparent manner. Traditionally, scoping reviews did not aim to assess the quality of research in the field, so gaps in knowledge due to poor quality research were not always revealed (Arksey and O'Malley, 2005), leading to some criticism of the overall value of this type of review (Grant and Booth, 2009). However, analysis of methodological quality has since been advocated (Daudt et al., 2013; Levac et al., 2010). It was considered to be an important undertaking to expose such potential gaps rather than exclude literature from the review, and enhance the opportunity to summarise and disseminate findings which may impact upon practice.

In its relative infancy, the scoping review method has been criticised as poorly defined and ambiguous (Daudt et al., 2013; Levac et al., 2010), though it's increasing presence in the research literature subjects it to continual clarification and framework development. A guiding framework was adopted to provide structure, rigour, consistency and replicability for this scoping review. Renowned frameworks for systematic reviews such as PRISMA (Moher et al., 2009) and that developed by the Centre for Reviews and Dissemination (CRD) (Centre for Reviews and Dissemination, 2009) were considered to be too precise to accommodate the range of research designs and lack of experimental studies likely to be retrieved for this review. Therefore, a more specific model for scoping reviews was sought. A Medline (1996 to 2015) database search for entries with ‘scoping review’ or ‘scoping study’ in the title revealed 217 English citations between 2004 and 2015, of which only 15 pre-dated 2010. Of fifty of the most recent studies available in full text scanned for evidence of use of a scoping review methodological framework, 15 (30%) did not state a published framework and 35 (70%) were based upon one advocated by Arksey and O'Malley (2005). Therefore, due to its popularity, evident lack of alternatives and recommendation by Colquhoun et al. (2014), this scoping review was conducted according to Arksey and O’Malley’s (2005) six stage framework. Reference to further refinements to enhance the methodology such as applying an iterative process to research question development and selection criteria, defining relevant concepts, and inclusion of quality indicators within the analysis was included (Daudt et al., 2013; Levac et al., 2010; Mays et al., 2005).

A key criticism of scoping reviews was the lack of clear and consistent reporting guidance, and Arksey and O’Malley’s (2005) framework did not present the level of detail required to sufficiently negate this. However, subsequent to the completion of this scoping review, the PRISMA-ScR checklist was published (Tricco et al., 2018). It was developed to direct researchers in conducting and reporting scoping reviews, to improve consistency, transparency and reproducibility, and against which the methodological rigour of published scoping reviews could be critically evaluated (Tricco et al., 2018; Colquhoun et al., 2014). The PRISMA-ScR is an adaptation of the original PRISMA statement and is said the be consistent with the Joanna Briggs Institute (JBI) guidance for scoping reviews (Tricco et al., 2018). The presentation of this scoping review conforms to the PRISMA-ScR adding confirmation of the methodological quality and transparency of this review (Tricco et al., 2018).

2.2 Methods

2.2.1 Stage 1 - Identifying The Research Question

Arksey and O'Malley (2005) do not impose strict limitations upon initial search terms but rather advocate an iterative process of reflexivity within each stage, allowing for potential development and redefinition of the focus of the search based upon increasing familiarity with the literature. However, the scope of this inquiry was clearly articulated by defining the key concepts, population, intervention and outcomes at the start to provide direction, clarity and focus for the subsequent stages of the process, and ensure that the research question remained clearly linked to the purpose of the scoping review (Tricco et al., 2018; Levac et al., 2010).

The research question was;

> ‘What is known about the way in which adult (>16 years) patients make decisions regarding implantation of complex cardiac rhythm management devices (CRMD)?’

The question was intentionally broad in nature to encourage breadth of coverage (Arksey and O'Malley, 2005). As the breadth of the initial question could result in a vast quantity and variety of studies, for example physician opinion on patient preferences, shared decision-making or information giving, while interesting would shift the focus away from the patient, ‘patient decision-making’ remained central to the study aim for inclusion in the review.

2.2.2 Stage 2 - Identifying Relevant Studies

A comprehensive set of key search terms and subject headings were devised (AMK, PM, JM), and applied across all search avenues between November 2014 and October 2016 (Appendix D). Plans to limit to English to avoid translation time and cost was not necessary, as foreign language citations were accompanied by an English translation. Limits from the year 2000 to reflect the fact that complex CRMD was not in mainstream practice until the mid-1990’s, also proved to be unnecessary as very few references pre 2000 emerged. To ensure breadth of coverage, eight databases particular to medicine, psychology, nursing and allied health publications, hand searching of various journals noted to be associated with either cardiology or decision-making, reference lists and authors, four grey literature databases and cardiac networks and organisations were included allowing inclusion of a range of study designs (Table 2.1) (Levac et al., 2010). The full Medline database search string can be found in Appendix E[1]. Google and Google Scholar searches for ‘implantable cardioverter defibrillator decision-making’ both revealed >17,000 hits, yet the first 100 titles were not specific to patient decision-making. In view of the need to balance comprehensiveness within time constraints (Daudt et al., 2013; Levac et al., 2010; Grant and Booth, 2009) both search avenues were abandoned. Citation tracking back via bibliographies and forward to papers citing studies were reviewed for relevance.

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1 The other database search strings are available in the supplementary information.

Table 2-1 Data Sources Searched, Number Of Hits And Papers Retrieved

Table 2.1 Data Sources Searched, Number Of Hits And Papers Retrieved From 25.11.14 to 3.10.16			
Date	**Database**	**Number Of Hits**	**Papers Retrieved**
27th November 2014	Cinahl (EBSCO Host)	768	41
28th November 2014	Embase (**Embase** 1996 to 2014 Week 47)	1401	31
25th November 2014	Medline (**MEDLINE(R)** 1996 to November Week 2 2014)	305	45
3rd October 2016	Medline (**MEDLINE(R)** (Limited to 2014 to 2016)	76	1
28th November 2014	PsycInfo (**PsycINFO** 1806 to November Week 4 2014)	13	13
4th December 2014	Scopus (Health Sciences; Life Sciences; Social Sciences & Humanities)	190	13
28th November 2014	Web of Science (All Databases)	568	44
25th November 2014	Cochrane Library	76	2
25th November 2014	Cochrane Database of Systematic Reviews	0	0
4th December 2014	Journals Searched Via Science Direct, Elsevier Search, Sage Publications BMJ, Lancet, EHJ, EJCN, JCN, American Journal Cardiology, Journal Of American College Of Cardiology (JACC), PACE, Circulation, Heart & Lung, Europace, Canadian Journal Of Cardiology, Patient Education & Counselling, Medical Decision-making, Health Expectations	30	30
11th December	Reference Lists Of Citations & Full Text Articles	13	13
11th December	Author Search	3	3
15 - 17th December 2014	Grey Literature Databases - http://www.opengrey.eu/ Proquest Dissertations, Conference Proceedings Citations Index, Conference Index	0	0
15th December	Cardiac Networks & Organisations, Policies & Guidelines BHF (0), NICE (1), DH NSF (1), DH NHS England (1), ESC (3), ACC/AHA (2)	8	8
		Total = 3451	**Total = 244**

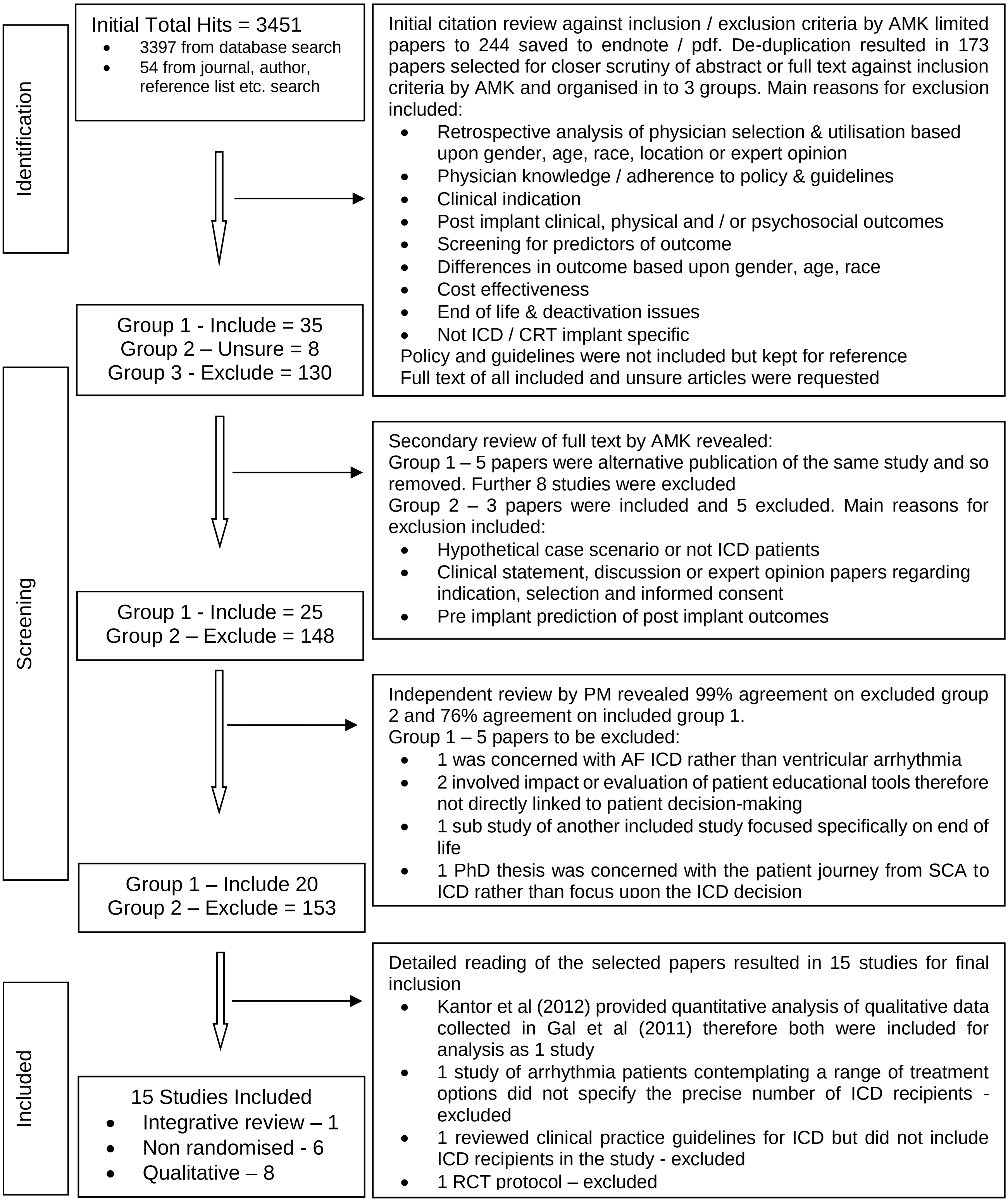
2.2.3 Stage 3 - Study Selection

Inclusion and exclusion criteria (Table 2.2) were collaboratively devised (AMK, PM, JM) (Levac et al., 2010). An initial independent assessment of a small selection of studies was undertaken (AMK & PM), to ensure agreement and discuss ambiguities or uncertainties. The criteria was then applied to all bibliographic citations and abstracts by AMK. In line with the principles of a scoping review, the inclusion criteria was deliberately broad and not restricted by study design (Armstrong et al., 2011). Detailed exclusion parameters were clearly set to ensure that patient decision-making related to rhythm management devices remained the focal point of the review, as dictated by the research question. To maintain the balance between '*feasibility, breadth and comprehensiveness*' p5 (Levac et al., 2010), refinement was made to the selection criteria, in response to increasing exposure to and familiarity with the literature. For example, 'ventricular' was included to avoid reference to other device therapy such as atrial pacing and defibrillation and a large proportion of the literature was concerned with clinical issues, post implant outcomes and physician decision-making necessitating expansion of the exclusion criteria. The full text was requested if the relevance of the study was unclear from the abstract, and for all studies included in the scoping review.

The title and abstract of 3451 references; 3397 from data bases and 54 from journal, author, reference list and organisation searches were retrieved, lending confidence to the view that scoping the field had been as comprehensive as possible. Considerable time was taken to search all titles for relevance against the inclusion criteria and 244 citations were retained and imported to Endnote v7 reference manager (Figure 2.1). Following de-duplication, 173 citations were selected for further scrutiny against the inclusion criteria by AMK and organised in to include (n=35), unsure (n=8) and exclude (n=130) groups. The full text of included and unsure articles were requested and reviewed. Alternative publications of the same dataset (n=5) were pooled and charted once and 13 were excluded resulting in 25 studies for inclusion and 148 to exclude. An independent review of the articles by PM revealed a 99% (147/148) agreement on the excluded studies and 76% (19/25) on the inclusion group. Discussion of initial disagreement resulted in 5 (21%) papers in the included group being excluded leaving 20 studies for the review. Moderation of any uncertainties by a third independent reviewer (JM) was not required.

Table 2-2 Inclusion And Exclusion Criteria Applied To Scoping Review

	Table 2.2 Inclusion Criteria Applied To Scoping Review
i.	Patients with serious life threatening cardiac illness who meet selection criteria for ICD for secondary or primary prophylactic prevention of life threatening **ventricular** arrhythmia or CRT for heart failure and at risk of life threatening arrhythmia
ii.	Age >16years to include adolescents
iii.	First time implant
iv.	Decision theory development or validation related to cardiac device therapy
v.	Individual and / or collective decision-making related to cardiac device therapy
vi.	Influential factors affecting acceptance or refusal of cardiac device therapy
vii.	Interventions e.g. decision aids to support decision-making related to cardiac device therapy
viii.	Development and validation of decision-making outcome measures related to cardiac device therapy
ix.	Any study design and applicable non research material - policy& guidance patient decision-making
	Exclusion Criteria Applied To Scoping Review
i.	Macro and meso-level healthcare policy and resource allocation for cardiac device therapy
ii.	Healthcare provider clinical decision-making including decision analysis, decision trees & physician (not patient focused) decision aids i.e. decision to refer for / offer device to patient
iii.	Physician decision regarding which device and therapy to offer e.g. CRT-P or CRT-D
iv.	Physician adherence to AHA, ESC, NICE policy and guidelines
v.	Retrospective analysis of physician selection and implantation based upon gender, age and race
vi.	Case studies of implantation for specific cardiac problems e.g. ARVD, Brugada, Long QT, HCM etc.
vii.	Mortality outcomes specific to demographic characteristics e.g. age gender, race
viii.	Audit of cost effectiveness of ICD
ix.	Clinical effectiveness e.g. Comparison of mortality outcomes with alternative management strategies
x.	Physician rating of the importance of patient preference in decision to offer ICD
xi.	Pre implant clinical assessment of need / indication e.g. Screening for potential SCA / SCD
xii.	Pre implant wearable automatic external defibrillator
xiii.	Comparison of endocardial, epicardial and subcutaneous (S-ICD) device placement; Bi versus tri ventricular lead placement
xiv.	Defibrillation testing during implantation
xv.	Pre implant predictive scoring of possible or optimal benefit
xvi.	Post implant physical, psychosocial, QOL outcomes such as anxiety, depressions, PTSD, and interventions such as CBT
xvii.	Post implant lifestyle restrictions e.g. work, driving, electromagnetic field, sport, athletes with ICD's
xviii.	Post implant technical follow up e.g. device interrogation, rhythm and therapy detection, assessment & therapy (re) programming
xix.	Comparison of post implant device parameters; technical issues, problems, concerns e.g. multiple shock, variable parameter settings etc.
xx.	Post implant complications e.g. infection, lead displacement or fracture, rationale for removal
xxi.	Post implant ablation or addition of adjunctive drug therapy
xxii.	Post implant remote monitoring strategies
xxiii.	Views on device re-use
xxiv.	End of life care decisions regarding deactivation of device, CPR, DNR, advanced directives
xxv.	Re-call and re-implantation issues
xxvi.	Access and participation into research trials
xxvii.	Treatment and care where issues of capacity were involved e.g. Critical care, unconscious / PVS & family / HCP advocacy & decision-making re continued treatment e.g. ventilation; Psychiatric or mental health treatment & care; Dementia; Parental decision-making on behalf of child
xxviii.	Complimentary / alternative therapies
xxix.	Help and / or treatment seeking
xxx.	Medication or treatment compliance & adherence



Initial Total Hits = 3451

- 3397 from database search
- 54 from journal, author, reference list etc. search

Initial citation review against inclusion / exclusion criteria by AMK limited papers to 244 saved to endnote / pdf. De-duplication resulted in 173 papers selected for closer scrutiny of abstract or full text against inclusion criteria by AMK and organised in to 3 groups. Main reasons for exclusion included:

- Retrospective analysis of physician selection & utilisation based upon gender, age, race, location or expert opinion
- Physician knowledge / adherence to policy & guidelines
- Clinical indication
- Post implant clinical, physical and / or psychosocial outcomes
- Screening for predictors of outcome
- Differences in outcome based upon gender, age, race
- Cost effectiveness
- End of life & deactivation issues
- Not ICD / CRT implant specific

Policy and guidelines were not included but kept for reference
Full text of all included and unsure articles were requested

Group 1 - Include = 35
Group 2 – Unsure = 8
Group 3 - Exclude = 130

Secondary review of full text by AMK revealed:
Group 1 – 5 papers were alternative publication of the same study and so removed. Further 8 studies were excluded
Group 2 – 3 papers were included and 5 excluded. Main reasons for exclusion included:

- Hypothetical case scenario or not ICD patients
- Clinical statement, discussion or expert opinion papers regarding indication, selection and informed consent
- Pre implant prediction of post implant outcomes

Group 1 - Include = 25
Group 2 – Exclude = 148

Independent review by PM revealed 99% agreement on excluded group 2 and 76% agreement on included group 1.
Group 1 – 5 papers to be excluded:

- 1 was concerned with AF ICD rather than ventricular arrhythmia
- 2 involved impact or evaluation of patient educational tools therefore not directly linked to patient decision-making
- 1 sub study of another included study focused specifically on end of life
- 1 PhD thesis was concerned with the patient journey from SCA to ICD rather than focus upon the ICD decision

Group 1 – Include 20
Group 2 – Exclude = 153

Detailed reading of the selected papers resulted in 15 studies for final inclusion

- Kantor et al (2012) provided quantitative analysis of qualitative data collected in Gal et al (2011) therefore both were included for analysis as 1 study
- 1 study of arrhythmia patients contemplating a range of treatment options did not specify the precise number of ICD recipients - excluded
- 1 reviewed clinical practice guidelines for ICD but did not include ICD recipients in the study - excluded
- 1 RCT protocol – excluded

15 Studies Included

- Integrative review – 1
- Non randomised - 6
- Qualitative – 8

Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. 2009. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement (Moher et al., 2009)

Figure 2-1 Flow Diagram Of Study Selection Process

Appendix F includes the full reference for the final 15 studies. Once detailed reading commenced it became apparent that the number of included studies could be condensed further. Kantor et al. (2012) represented a quantitative analysis of codes and categories derived from the already included qualitative study by Gal et al. (2011). They were therefore merged for the purpose of the scoping study. Langseth et al. (2012) was not specific to ICD and CRT but included arrhythmia patients contemplating various arrhythmia treatment options and as the researchers did not clarify precisely how many were considering ICD, it was excluded. An RCT protocol for a study currently underway was excluded and another study reviewed clinical practice guidelines for ICD, but did not include ICD recipients requiring its exclusion. Matlock et al. (2012) referred to a sub group study of an ongoing larger research initiative concerned with development of a tool to measure the quality of decision-making around ICD’s. The sub group study involved a survey comparison of opinion leaders and ICD patients importance rating of fact and value items related to ICD decision-making. However, as it was available as a conference abstract only, there was insufficient methodological information to facilitate its inclusion in the review. The selection process including main reasons for exclusion which resulted in 15 studies for final analysis is outlined in a flow diagram (Figure 2.1). The original search terms were repeated at regular intervals between 2016 and October 2019. No further literature matching the scoping review inclusion criteria emerged.

2.2.4 Stage 4 - Charting The Data

The challenge of scoping reviews lies in the ability to present a large volume of data in a meaningful way (Arksey and O'Malley, 2005). Arksey and O'Malley (2005) refer to ‘charting’ as opposed to ‘data extraction’ described as a technique for sorting, organising and charting data in to key issues and themes to enable synthesis and interpretation of qualitative data (Ritchie and Spencer, 1994). The ‘descriptive-analytical’ method often used within the narrative tradition is recommended for collection of standard information from each study. A detailed data chart collectively devised on Excel (AMK, PM, JM) was divided by research tradition and organised alphabetically by author (Appendix G). General study information extracted from the primary studies included author, date, study location, publication and journal impact factor derived from https://www.citefactor.org/page/Impact-Factor-2017-2018-j.html. Specific study information including research design, aims, sample size and selection criteria, data collection method and key findings were extracted. As with previous stages, an iterative approach was adopted to allow constant updating of the data charting form (Levac et al., 2010). AMK populated the data chart negating inter-reviewer reliability issues and adding confidence to the consistency of the data chart with the research question and purpose (Daudt et al., 2013). Reflexivity and continual reporting of uncertainties and rationale for changes were agreed at regular meetings with PM and JM to maintain openness and transparency. For example, specific information relating to intervention, outcome measure and theoretical frameworks only applied to one or two studies and was therefore subsumed within aims or data collection methods. The data chart provided a detailed overview of methods to assist identification of commonalities, themes and gaps in the literature (Armstrong et al., 2011).

2.3 Findings

2.3.1 Stage 5 - Collating, Summarising And Reporting The Results

A clear and consistent methodological approach to data analysis is an essential aspect of rigour and transparency in the scoping review (Tricco et al., 2018; Daudt et al., 2013; Levac et al., 2010; Arksey and O'Malley, 2005). Yet, in a methodological review of scoping studies, Davis et al. (2009) described the methods of data analysis employed as either '*poorly formulated, poorly described or absent*' p.1393, suggesting this was often the weakest element of scoping reviews. Arksey and O'Malley (2005) advocate presenting a descriptive numerical summary of key characteristics of included studies and acknowledge the need for some form of thematic analysis to present a narrative account of the literature, however they offer very little by way of further explanation of how this may be constructed. While several approaches to primary quantitative and qualitative data analysis exist, few have been adapted for evidence synthesis and those that are available tend to be specific to either quantitative or qualitative data rather than both (Mays et al., 2005). Mays et al. (2005) described four approaches to synthesis based upon data type. They were quantitative reliant upon statistical pooling such as meta-analysis, Bayesian meta-analysis, qualitative such as meta-ethnography and narrative approaches. The narrative approach is recommended when the review question relies upon inclusion of different research designs, producing qualitative and quantitative findings and non-research evidence which are not readily amenable to meta-analysis or meta-ethnography (Mays et al., 2005). In this review, the numerical data lacked sufficient homogeneity to warrant further statistical meta-analysis, therefore study findings were subject to narrative scrutiny only.

Table 2-3 Descriptive Analysis Of the Included Studies

Author & Design	Sample Size	Male n (%)	Female n (%)	Age - Mean or Median : (SD) :Range	Primary ICD	Secondary ICD	CRT	Accept Device	Decline Device	Ethnicity	Interval From Implant To Study	MMAT
Qualitative Study Descriptive Analysis												
Agard et al 2007 Grounded Theory	31	25 (81%)	6 (19%)	Mean 65 44-79	-	31	-	31 (100%)	-	?	Mean 40 months (61% no shock)	75%
Carroll et al 2011 Grounded Theory	44	33 (75%)	11 (25%)	Mean 65 (12.5) 26-87	34	-	-	34 (27M : 7F)	10 (6M : 4F)	(65% Retired; 64% IHD)	Accept - 1 month Decline up to 1 month	100%
Gal et at 2011 (GT) (& Kantor et al 2012)	191	140 (73%)	51 (27%)	Median 60's 19 - 92	?	?	?	191 (100 %)	-	White 71%, AA & Hispanic	Mean 5.39 years (61% no shock)	50%
Lucas 2012 Phenomenology	8	6 (75%)	2 (25%)	Mean 84 71-93	3 (+ 3 Unknown)		2	8 (100%)	-	Caucasian 100% (Jewish 75%)	1 to 16 years (50% > 6 years)	50%
Matlock et al 2010 Descriptive	22 HF	16 (73%)	6 (27%)	Mean 69	12 (55%)		7 (32%)	19 had a device	-	?	3 patients did not have CRMD	100%
Matlock et al 2011 Descriptive	20 Pt 11 Phys	12 (60%)	8 (40%)	Mean 59 34-72	14	-	-	14 (70%)	6 (30%)	White (65%) Black (25%) Native American (5%) Hispanic/Latino (5%)	?	100%
Ottenberg et al 2014 Descriptive	13	11 (85%)	2 (15%)	Med 65 44 - 88	12 Offered	-	1 Offered	-	13 (100%)	White 100% (10 77% Married)	Not applicable	100%
Yuhas et al 2012 Grounded Theory	25	18 (72%)	7 (28%)	Mean 69+3yrs 35-94	12 (48%)	-	-	12 (48%) 4F : 8M	13 (52%) 3F : 10M	White 100%	Pre Implant	100%
Quantitative Study Descriptive Analysis												
Chan et al 2016 Retrospective Cohort	240	202 (84%)	38 (16%)	Mean 61.2 (9.7)	240 Offered	-	-	-	240 (100%)	Chinese (71%), Malay (16%), Indian (11%), Other (2%)	Not applicable	75%
Groarke et al 2012 Retrospective Cohort	75	62 (83%)	13 (17%)	Median 64 (9.4) 29-82	69 (92%)		6 (8%)	75 (100%)	-	?	Med 36 months (SD 1.9) 1-9 years	100%
Hauptman et al 2013 Retrospective Cohort	41 Pt 11 Phys	20 (49%)	21 (51%)	Mean 61.4 (14.7)	12 (29%)	29 (71%)		20 (49%) had >1 device procedure e.g. upgrade, recall, generator change		?	1 to 11 years	50%
Hazelton et al 2014 Prospective Cohort	103	67 (65%)	36 (35%)	Mean 54.86 (9.4) 19-90	? All Primary	-	-	-	-	Mixed Race (53.3% Married)	Pre Implant	75%
Hickman et al 2010 & 2012 Retrospective	109	83 (76%)	26 (24%)	Mean 65.64 (13.58)	92 (88%)	13 (12%) (4 Unknown)	-	109 (100%)	-	Caucasian 79 (72%) Non Caucasian 30 (28%)	Mean 18 months (SD 0.75)	75%
Singh et al 2012 Retrospective Cohort	50	?	?	Mean 62 +11 yrs	29	-	-	29 (58%)	21 (42%)	Caucasian 27 (54%) Africa Am 18 (36%) Asian 5 (10%)	?	-
Lewis et al 2014 Integrative Review	-	-	-	-	-	-	-	-	-	-	-	-

2.3.2 Descriptive Overview Of Methodological Approaches

Of the 3451 citations retrieved, 15 studies fulfilled the conditions for inclusion. Table 2.3 presents a condensed numerical analysis of the extent, nature and distribution of the research. Eight qualitative studies (3 descriptive, 4 grounded theory and 1 phenomenological approach), six non randomised cohort trials (5 retrospective, 1 prospective) and an integrative review were published between 2007 and 2016. All studies were conducted in North America (USA or Canada) with the exception of Agard et al. (2007) (Sweden), Groarke et al. (2012) (Ireland) and Chan et al. (2016) (Singapore).

Sample sizes were small ranging from eight (Lucas, 2012) to 240 (Chan et al., 2016) patients post CRMD recommendation. The quantitative studies used random selection (Groarke et al., 2012; Singh, N. et al., 2012) or convenience sampling and qualitative studies describe purposive sampling. Several studies recruited from either local or national registers or more than one implant centre (Hazelton et al., 2014; Hauptman et al., 2013; Yuhas et al., 2012; Groarke et al., 2012; Carroll et al., 2011; Gal et al., 2011;) enhancing heterogeneity of the patient group. However, sampling bias on the basis of willingness or not to participate particularly with respect to decliners was acknowledged by Ottenberg et al. (2014) and Yuhas et al (2012). A ratio of 2-4 men to 1 woman were represented with the exception of 1:1 in Hauptman et al. (2013). Mean age ranged from 54.86 to 69 years with the exception of Lucas (2012) who targeted older adults (mean 84 years). Six studies (Chan et al., 2016; Hazelton et al., 2014; Singh, N. et al., 2012; Matlock et al., 2011; Gal et al., 2011; Hickman et al., 2010 and 2012) included mixed race participants though the majority were Caucasian and other demographic information such as marital status, and educational level was scarcely reported.

One study (n=31) focused upon secondary ICD (Agard et al., 2007), seven (n=495) on primary ICD (Chan et al., 2016; Ottenberg et al., 2014; Hazelton et al., 2014; Singh, N. et al., 2012; Yuhas et al., 2012; Carroll et al., 2011; Matlock et al., 2011) and five (Hauptman et al., 2013; Groarke et al., 2012; Lucas, 2012; Hickman, 2010; Matlock et al., 2010) included both ICD indications. Five studies included ICD and CRT (Ottenberg et al., 2014; Hauptman et al., 2013; Groarke et al., 2012; Lucas, 2012; Matlock et al., 2010) and it was not clear which indication or device type Gal (Gal et al., 2011) referred to. Four studies (Singh, N. et al., 2012; Yuhas et al., 2012; Carroll et al., 2011; Matlock et al., 2011) compared patients who accepted and declined devices, six (Groarke et al., 2012; Lucas, 2012; Gal et al., 2011; Hickman, 2010; Matlock et al., 2010; Agard et al., 2007) studied acceptors only and two (Chan et al., 2016; Ottenberg et al., 2014) focused upon those who refused CRMD's. Matlock et al., (2011) also interviewed physicians and Lucas (2012) explored the lived experience of older adults decision to accept device therapy.

With the exception of one study (Hickman Jr et al., 2012; Hickman, 2010) non-standard, researcher designed instruments with unconfirmed validity and reliability, were employed to explore decision styles, influencing factors, patient knowledge, decisional control preference, satisfaction and regret. Groarke et al. (2012) make the questionnaire available however it was not clear whether patients selected from a pre-defined list of ICD functions and complications or whether they had to volunteer from memory which may have affected recall of information. Hickman et al. (2010 and 2012) used various standardised, pre-validated scales e.g. Miller Behavioural Style Scale (MBSS), Decisional Control Preferences (DCP) Scale, Medical Outcomes Survey (MOS-SF), Profile Of Mood State (POMS) and Decisional Regret Scale (DRS). Hickman et al (2010 and 2012) aimed to assess the validity of the DRS, but they do not include analysis of decision regret among decliners or consider indication or device type.

A range of data collection methods including telephone interview (Groarke et al., 2012; Yuhas et al., 2012; Gal et al., 2011; Hickman et al., 2010 and 2012), focus group interview (Ottenberg et al., 2014; Hauptman et al., 2013) or individual face to face (all others) were employed. In-depth semi structured interviews making greater use of open ended questions and probes were described in the qualitative studies. Yuhas et al. (2012), Carroll et al. (2011) and Matlock et al. (2011) provide more detail on their interview schedules to aid replication. Carroll et al. (2011) describe revision of their interview schedule three times during the study in response to data familiarisation and in line with the principles of grounded theory. Gal et al. (2011) describe using open ended questions however examples of topic areas given suggest a more structured approach than expected. The potential impact of telephone rather than face to face and different interviewers upon participant responses was acknowledged by Gal et al. (2011). Hauptman et al. (2013) video recorded patient-physician interactions however reliance upon a structured data abstraction tool developed by the researchers may have minimised the potential to capture all verbal and non-verbal information. They do acknowledge the potential Hawthorne effect arising from observation, though do not make reference to the limitations associated with use of simulated patients and hypothetical situations. Singh, N. et al., (2012) used a standardised interview and rating scale though further details are unavailable.

With the exception of two prospective studies (Hazelton et al., 2014; Yuhas et al., 2012), retrospective data collection occurred between one and sixteen years post implant (except Carroll et al 2011). Where there is delayed follow-up, the validity of the findings could be questioned as recall of the detail surrounding the decision-making experience may have been affected. For example, Hauptman et al. (2013) does not state how long post implant but notes that 20 patients (49%) had experienced two or more device related procedures such as upgrade, revision or generator replacement.

Data saturation was said to be reached by some (Yuhas et al., 2012), whereas Agard et al. (2007) restricted transcription to thirteen interviews which may have limited full immersion, saturation and therefore potential loss of key elements. Matlock et al. (2011) failed to reach data saturation among decliners due to small sample size. The qualitative studies provide detail and direct participant quotes to demonstrate and support determination of codes, categories and themes. Some refer to the gender, age and device type of participants though not all and sample sizes limited the opportunity to make any further inferences on potential impact of demographic differences or quantitative comparison between ICD acceptors and decliners.

Unlike the systematic review concerned with the collation of high level evidence, through comparison, analysis and synthesis of the quality and relative value of a limited selection of evidence, this review aimed to determine the breadth of what is known about ICD decision-making, with more cursory reference to the rigour and quality of the research. As there is a lack of consensus and guidance on quality criteria applicable to studies across different methodologies, appraisal of the methodological quality was undertaken to provide a sense of the overall merit of the evidence presented, rather than as a means to exclude studies from the review (Mays et al., 2005). The diversity of research designs adopted to study ICD patient decision-making and issues of instrument validity and reliability presented challenges in terms of the choice of critical appraisal tool. The UK Centre for Review and Dissemination (CRD) (Centre for Reviews and Dissemination, 2009) advocate structured criteria against which the quality assessment of studies can be measured and recognise a range of well used quantitative critical appraisal methods, though acknowledge the wide variation in tools available for the evaluation of qualitative and mixed methods approaches. A review of 44 critical appraisal tools found that 33 (75%) measured content validity, but only seven (15.9%) considered concurrent and / or construct validity and ten (22.7%) reliability, leading the authors to conclude that the design, development and testing of many tools failed to adhere to basic research techniques, leading to a general lack of rigor (Crowe, M. and Sheppard, 2011).

One such recently developed tool, the Mixed Methods Appraisal Tool (MMAT)[2] (Pluye et al., 2009), was selected for its ease of application, simplicity and capacity to allow independent evaluation of quantitative and qualitative studies, based upon four criteria specific to their research design, and a combination of the appropriate components of both for mixed method studies. Each of the criteria attracts 1 point (25%) up to a maximum of 4 (100%) and mixed methods scores cannot be greater than the score allocated to the weakest element. Pilot testing reported an intra-class correlation of 0.80 supporting its use as a valid method of analysis across research designs (Crowe, M. and Sheppard, 2011; Pluye et al., 2009). Pace et al. (2012) subsequently reported substantial reliability between reviewers for the overall quality scoring of appraised studies, recommending its use for further testing and development for systematic mixed studies reviews. It was established as a practical, effective and easy tool for quality assessment of a mixed methods review by Lewis et al. (2014a) and Dahan-Oliel et al. (2012) though neither provided further analysis of the validity or reliability of the tool.

Quality assessment was calculated for each study in the review. Appendix H provides a detailed appraisal of the strengths and weaknesses of the scoping review studies. Overall, the level of reporting was variable but sufficient to enable quality assessment for all except one conference abstract (Singh, N. et al., 2012), providing limited methods information and the integrative review (Lewis et al., 2014a), which included an independent, comparative MMAT assessment. Of thirteen appraised studies, six scored 100%, four scored 75% and three 50% (Table 2.3).

2.3.3 Qualitative Thematic Analysis

Thematic analysis, commonly adopted within the traditional narrative review to enable basic synthesis of findings across studies was selected. It allows clear identification and merging of recurrent commonalities and development of themes arising from the literature, without total loss of integrity of the original data (Hsieh and Shannon, 2005; Mays et al., 2005). It is valued and appropriate when the review question dictates the inclusion of a wide range of research designs producing quantitative and qualitative findings (Snilstveit et al., 2012; Fereday and Muir-Cochrane, 2006). Although it offers flexibility and inclusiveness it has been criticised for being less systematic and explicit (Dixon-Woods et al., 2004). In contrast, narrative synthesis increasingly evident in the literature, moves beyond the simplicity of the traditional narrative review in attempting

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[2] The Mixed Methods Appraisal Tool (MMAT) is available in the supplementary information.

to synthesise findings in an effort to generate new knowledge, insights or theory in a more systematic, transparent and therefore replicable manner (Popay et al., 2006; Mays et al., 2005). It seeks to interrogate patterns arising from the literature in order explore relationships within and across the included studies (Popay et al., 2006). The intention of this scoping review was to reveal the breadth of what is and is not known about patient decision-making rather than make inferences about who, how, why, when and where, therefore an abridged narrative synthesis was undertaken.

The selected papers were scrutinised for similarities and differences by data mapping, coding and comparison of consistently used words, phrases, concepts and ideas. The study aims revealed two overarching areas of interest related to the process of decision-making and device knowledge acquisition and recall. These were defined as Cluster 1 and 2, in order to differentiate them from the term ‘themes’ later referred to in the Chapter 5 Strand 2 framework analysis. Further scrutiny of the study findings established six ‘sub-themes’ within each cluster. The clusters and sub themes were summarised and organised in to table 2.4.

Table 2-4 Emergent Sub Themes Established Within The Clusters

Table 2.4 Emergent Sub Themes Established Within The Clusters

	Cluster And Sub Themes	Researcher	Study Aims And Findings
1	**The Process Of Decision-making** 1.1 Approaches To Decision-making 1.2 Factors Influencing The Decision Style 1.3 Accepting Or Refusing Device Therapy 1.4 Decisional Outcomes	Agard et al. (2007) Grounded Theory	Explored patients with heart failure and previous life threatening arrhythmia **experience** and **perception** of role in secondary ICD decision-making. 1 way Dr to Patient communication. Facing a matter of fact - patients heeded recommendation of need for ICD. 'An offer you cannot refuse'. Patients accepted physician recommendation for ICD as having no real choice if they valued longevity. Patients view themselves as laymen unable to have opinion of complex medical decision. Many desire to live longer so willing to accept technology despite poor prognosis, risks or inconvenience. Trust Dr judgement so accept recommendation. Negative experiences with ICD but did not **regret** implant decision because device increased chance of staying alive.
		Carroll et al. (2011) Grounded Theory	Explored the decision-making **process** for patients who **accepted and declined** primary ICD DM triggered when assimilated risk of SCD. Physician recommendation & new awareness of SCD risk motivated acceptance. Pts occupy position somewhere along continuum between 'active & engaged' -'passive & indifferent' decision-making. Approach adopted largely **influenced** by 1) trust; 2) social influences;3) patient's health state. Main goal was to prolong life. Degree of activity or passivity in DM did not influence likelihood to accept / refuse ICD
		Chan et al. (2016) Non Randomised Descriptive	Explored **perception** of primary ICD to understand barriers to acceptance for patients who **accepted and declined** primary ICD. Major themes: 1) Personal risk; 2) Strength of recommendation; 3) Concerns over recall, malfunction, and surgical risk; 4) Feelings regarding invasive life-prolonging interventions played important role in ICD referral refusal. No significant demographic or clinical difference between participants & non participants and between acceptors and decliners Explored demographic and social **factors that influenced** patients decision to **decline** 98% relied upon physician information only. 2% sought additional information from internet and publications Most (61%) believed they were most important person influencing decision, 15% felt that Dr played most important role. All refused because: cost (27%), invasive nature of procedure (24%), fear of complications (11%) advancing age (9%). Traditional factors associated with acceptance of more aggressive treatment i.e. younger, disease duration, educational attainment, salary were not evident. Strength of physician recommendation did **influence** decision i.e. weak recommendation associated with refusal. Chan conclude this may have been associated with passivity in information gathering. 65% did not **regret** decision, remaining unwilling to accept, 35% might agree to ICD in the future. Those most likely to reconsider were employed (possible financial reasons), feared SCD the most and acknowledged ICD preventative role

Table 2.4 Emergent Sub Themes Established Within The Clusters

	Cluster And Sub Themes	Researcher	Study Aims And Findings
1	**The Process Of Decision-making** 1.1 Approaches To Decision-making 1.2 Factors Influencing The Decision Style 1.3 Accepting Or Refusing Device Therapy 1.4 Decisional Outcomes	Matlock, DD. et al. (2010) Descriptive	Explored patients with heart failure perceptions of difficult decisions and **factors that influenced** treatment decision-making (most had ICD or CRT). Described two distinct **approaches** to DM - 1) 'Active' associated with difficult decisions; participants considered & weighed up concerns related to side effects, family and overall QOL; required time to reflect & wanted second opinion. 2) 'Passive' did not identify difficult decision, described influencing factors as trust in God, physician and power of physician. Some passive DM believed all medical therapies helpful; others disengaged from medical care altogether.
		Matlock, DD. et al. (2011) Descriptive	Explored patient and physician **perception** of decision-making for patients who **accepted and declined** primary ICD (includes refusal of secondary ICD). Patients who chose ICD - 3 themes 1) Desire to avoid death; 2) Need to follow physicians advice; 3) Discovery of risks post implant. Many **accepted** ICD on physicians advice without questioning benefit and risks.
		Ottenberg, A. et al. (2014) Descriptive	Patients who **refused** ICD - 1) Considered ICD to be unnecessary or believed risk of SCD did not apply to them 2) Perception that burden outweighed benefit. Physicians describe 2 main **approaches** - beneficent paternalistic and patient centred, shared approach.
		Singh, N. et al. (2012a) Non Randomised Descriptive	Quality of life more important than quantity. Religious belief and cultural values did not play major role in DM. Good access to health care resources & physicians. Women less likely to be married. Only 2 (7%) ICD patients would not accept ICD again; 18 no ICD (86%) pts would later reconsider implant.
		Yuhas et al. (2012) Grounded Theory	Explored **reasons** why patients **declined** primary cardiac device therapy. Major themes 1) 'Don't mess with a good thing'; 2) 'My health is good enough'; 3) 'Making independent decisions'; 4) 'It's your job, but it's my choice'. Decliners described as collecting information from Dr and others to make informed decision & needed time to analyse and reflect - thus active DM. Patients who declined considered physician recommendation of need for device to be less influential than the way they felt. Patients considered DM to be a process not one off episode therefore some would re deliberate in future.

Table 2.4 Emergent Sub Themes Established Within The Clusters

	Cluster And Sub Themes	Researcher	Study Aims And Findings
2	**Device knowledge acquisition and recall** 2.1 Insight Into Condition, Device Role And Function 2.2 Physician Communication And Information Received	Agard et al. (2007) Grounded Theory	Minimal criticism of lack of information or passive role played in DM. Participants agreed all they needed to know was they were high risk of life threatening arrhythmia to give consent. Did not recall discussion of alternative options; estimate of risk of potential fatal arrhythmia or expected time of survival with HF. Patients appeared not to need more information when related to life & death decisions and where no alternative option appeared to exist. Patients believed they had sufficient information to consent. They credited the device with saving their life despite not receiving shock therapy, believed it prevented further cardiac events or relieved symptoms.
		Carroll et al. (2011) Grounded Theory	General lack of understanding of ICD role & function related to condition & symptoms. Participants did not recall receiving information related to alternatives to ICD therapy.
		Chan et al. (2016) Non Randomised Descriptive	Retrospective study to explore **knowledge** and **influencing factors** in decision to **decline** primary ICD. Perceived consequence of heart failure said to be stroke (42%), SCD (28%), MI (17%), don't know (14%). 68% believed medication could prevent SCD, 16% believed exercise and diet could prevent SCD. Only 8% understood SCD preventative role. When asked about ICD function 52% correctly answered SCD prevention, 48% were not aware of SCD preventative role. Most feared consequence of heart failure was being bed bound (37%), breathlessness (30%), SCD (17%), chest pain (8%), don't know (8%). All believed ICD would restrict life style including inability to do heavy lifting (30%), problems with electrical devices (17%), flying (10%), swimming (12%), sexual activity (5%) Chan conclude that limited consultation time, language barriers, deep seated beliefs that contradict physician advise could explain lack of understanding.
		Groarke et al. (2012) Non Randomised Descriptive	Retrospective cohort study to explore the **knowledge**, understanding and view of patients with (primary/secondary) ICD or CRT device. 83% (62 of 75) claimed to understand reason for ICD implant. Sub group - no patient suggested arrhythmia termination; inferred arrhythmia related reason; heart failure; various reasons including reducing risk of 'heart attack'; unable to state reason other than physician recommendation. Excluding CRT patients recipients incorrectly believed device would improve cardiac function, breathing, exercise capacity, reduce risk of heart attack or stopping breathing. Shock recipients poorly prepared for shock therapy. 79% claimed to have sufficient information to consent. Patients who experienced device-related complication felt inadequately forewarned of complications. Despite pre implantation education, patient comprehension of risks & benefits of ICD therapy is poor and expectations of ICD therapy may be inappropriate.

Table 2.4 Emergent Sub Themes Established Within The Clusters

	Cluster And Sub Themes	Researcher	Study Aims And Findings
2	**Device knowledge acquisition and recall** 2.1 Insight Into Condition, Device Role And Function 2.2 Physician Communication And Information Received	Hauptman et al. (2013) Non Randomised Descriptive	Retrospective study to explore patient **knowledge** and **physician communication** of information during decision-making for cardiac device therapy (precise indication and device type unclear). Mean (SD) estimated number of patients out of 100 who would be saved by the ICD was 87.9 (20.1). Mean (SD) rating of preparedness for 39 patients was 5.7 (3.2) out of 10 at the time of the implant procedure and during the patient focus group meeting. Did not recall discussion of peri-procedural risk or post implant complications. Limited discussions on QOL issues which focused upon fact that ICD would have no lifestyle effect. QOL measures not used pre or post implant. Pre implant mention of anxiety or depression infrequent. Gained knowledge of benefits and risks post implant. SP interviews focused medical history & procedure-related processes in context of medical benefit of ICD. Patients largely uniformed and overly optimistic about future expectations with ICD. Patient group consistently note inadequacy of information received pre implant and inattention paid to psychosocial issues post implant
		Hazelton et al. (2014) Non Randomised Descriptive	Prospective study to develop and test a measure (**ICD-DAS**) of patient evaluated ICD pros and cons and its impact upon patient decision-making for a primary ICD or CRT (precise indication and device type unclear). Two-factor measure for ICD decision-making established with two subscales: ICD Pros and ICD Cons. ICD – DAS provides empirically tested & clinically useful pros & cons scale to help patient decision-making.
		Lewis et al. (2014a) Review	Pt's with ICD misunderstood functionality or over-estimated benefit. Recommend physicians better support patients by 1) verifying understanding; 2) eliciting preferences; 3) promoting shared decision-making
		Lucas (2012) Phenomenological	Limited information about device role, function & what they may expect. Some felt information was beyond their comprehension and most failed to seek additional information.
		Matlock, DD. et al. (2011) Descriptive	Recipients reported not knowing about side effects until after device implant or when they experienced side effects. Physician communication with ICD patients – 3 themes 1.Considerable variation existed in approach to patient centeredness and communication; 2. Physicians influenced by benefits presented in published guidelines; 3. Discussion revealed clear hierarchy in which physicians emphasised benefits but emphasis of risks varied greatly. Physician adherence to guidelines appeared to inhibit SDM.

Table 2.4 Emergent Sub Themes Established Within The Clusters			
	Cluster And Sub Themes	Researcher	Study Aims And Findings
2	**Device knowledge acquisition and recall** 2.1 Insight Into Condition, Device Role And Function 2.2 Physician Communication And Information Received	Ottenberg, A. et al. (2014) Descriptive Singh, N. et al. (2012a) Non Randomised Descriptive Yuhas et al. (2012) Grounded Theory	'Gaps in learning' – identified gaps in knowledge, participants keen to have all information. Physicians perspectives refers to agreement between patients view of refusal and what physicians had documented in medical notes as reason for non-implant. Physicians unaware that patients lacked knowledge of purpose & function of ICD. Prospective study to explore **knowledge** and **influencing factors** in decision to **accept or decline** primary ICD (precise indication and device type unclear). ICD pts and no ICD pts understanding of HF was poor. No ICD pts had less understanding of ICD purpose, were less likely to have been given written ICD information, less likely to recall recent discussion on ICD's. Underutilization of primary ICD's may be related to limited communication & poor understanding of HF, sudden death & devices. Inaccurate perceptions of ICD-related risks and lifestyle limitations. Acceptors and decliners had reasonably good understanding of purpose & function of ICD

2.3.4 Cluster 1: The Process Of Decision-making

Acknowledgement of 'ICD candidacy' and an appreciation of the risk of SCD evoked feelings of fear and uncertainty of benefits and risks presenting a powerful motivator to initiate the process of decision-making (Carroll et al., 2011; Gal et al., 2011; Agard et al., 2007). Of 75 cardiac device recipients, 26 (35%) reported feeling frightened when informed of the requirement for CRMD (Groarke et al., 2012). The initial response to the news provoked very different levels of patient engagement with decision-making.

Sub Theme 1.1 Approaches To Decision-making

The literature identified a combination of approaches reflecting the interplay between individual and collective decision-making. Physician recommendation for CRMD initiated a passive, indifferent approach for 10 (45%) patients with heart failure (Matlock et al., 2010) and 35 (47%) ICD recipients (Groarke et al., 2012). Passive decision-makers accepted the decision quickly, sought little additional information or time to deliberate due to fear or disinterest akin to non-systematic heuristic information processing. They described one way physician-patient communication and devolved decision-making to expert medical opinion and or family and significant others (Hauptman et al., 2013; Groarke et al., 2012; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007). Chan et al. (2016) reported that 235 (98%) relied solely upon expert opinion for information. Whereas, Matlock et al. (2010) revealed an almost 50:50 split between passive and active decision makers and Groarke et al. (2012) reported a group of 21 (28%) participants who described joint decision-making between the physician and themselves (Table 2.5).

Twelve (55%) participants in Matlock's study (2010) and 19 (25%) (Groarke et al., 2012) who adopted an active approach, appeared to invest time to systematically seek further information and second opinions from a range of sources, take time to fully comprehend the function, the balance of benefit and risk and develop trust in the device to reach a decision (Ottenberg et al., 2014; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007). Participants who declined an ICD described making 'independent decisions' after careful deliberation of the benefit and burden though also acknowledged the experience of others as a potential influence (Ottenberg et al., 2014; Al-Khatib et al., 2011).

Table 2-5 Level Of Involvement In Decision-making

	ICD Matlock et al. (2010)	ICD Groarke et al. (2012)	
		Desired Involvement	Actual Involvement
Traditional passive paternalistic model	(10) 45%	(40) 53%	(35) 47%
Shared decision-making (SDM)			(21) 28%
Active informed (patient) model	(12) 55%	(35) 47%	(19) 25%
Total	(22) 100%	(75) 100%	

Rather than distinct approaches, Carroll et al. (2011) described participants as occupying a position somewhere along a continuum between ‘passive, indifferent’ and ‘active, engaged’ decision-making. Some recipients desired active involvement in knowledge and information exchange but relinquished responsibility for the final decision to the physician (Agard et al., 2007). Thus, information transfer appeared to be the crucial element of, and synonymous with, involvement in decision-making rather than deliberation, choice and implementation of the final decision (Carroll et al., 2011). However, the extent to which some ICD patients were sufficiently informed to consent was questioned (Hauptman et al., 2013; Carroll et al., 2011). Others made ‘independent decisions based upon their preferences while acknowledging guidance by physician recommendation or the experience of others as a potential influence (Ottenberg et al., 2014; Matlock et al., 2011; Carroll et al., 2011).

Groarke et al. (2012) was the only study to consider the relationship between levels of desired and actual involvement. 40 (53%) patients desired passive involvement and 35 (47%) patients reported that the decision had been made by the physician. 35 (47%) preferred an active role but only 19 (25%) reported making independent choices and 21 (28%) believed it had been a joint decision though further analysis of the exact nature and extent of different interactions was not expanded upon.

Sub Theme 1.2 Factors Influencing The Decision Style

Individual characteristics and the degree of importance assigned to various situational factors appeared to influence the level of engagement in decision-making. Older adults contemplating device therapy were more inclined to passivity (Hauptman et al. 2013; Lucas, 2012). ‘Trust and faith in their physician’ ‘wish to live’ ‘acceptance, ease of decision' 'limited information and involvement' 'lack of an option' were described and involvement of family members in decision-making was an exception which was outweighed by physician advise (Lucas, 2012). In contrast, Hauptman et al. (2013) suggested that older participants were more likely to defer the decision to family members. Despite little mention of potential gender differences, Kantor et al. (2012) found that women were 2.7 times more likely to actively confirm their ICD decision to others than men. They were more likely to report 'no agency', emotional reasons and deem the physician to be a detailed information giver rather than authority figure as factors affecting decision-making than men.

Fear, uncertainty and perceived difficulty of the decision associated with physician recommendation for primary devices precipitated a passive approach (Ottenberg et al., 2014; Hauptman et al., 2013; Groarke et al., 2012; Lucas, 2012; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011). Passive decision makers did not identify a difficult decision (Ottenberg et al., 2014; Al-Khatib et al., 2011), or found it easy to make based upon 'facing a matter of fact' (Lucas, 2012; Agard et al., 2007) and 'accepting the device was necessary' (Lucas, 2012). A pervading sense of 'no choice' emanated from secondary ICD recipients perceived to have adopted a passive approach, accepting it as an 'offer you cannot refuse' and describing themselves as laymen unable to have an opinion on such complex medical decisions (Lucas, 2012; Gal et al., 2011; Agard et al., 2007). Agard et al. (2007) concluded that some secondary device recipients did not require further information when related to life and death decisions for which they perceived no alternative option, and the desire to live longer prompted acceptance of technology despite prognosis, risks or inconveniences. Alternatively, a perception that the decision was difficult to make presented a powerful motivator to actively engage in decision-making for others (Matlock et al., 2010).

Current health state, in particular the perceived severity of the event or symptom experience prompted some to passively accept advice quickly without further consideration of net benefits and risks (Lucas, 2012; Carroll et al., 2011; Gal et al., 2011; Matlock et al., 2010; Agard et al., 2007). Yet insufficient perception of severity of illness, symptomatology and minimised belief in potential risk of SCD and device necessity in those recommended for primary devices was also associated with passive indifference (Yuhas et al. 2012; Carroll et al. 2011; Matlock et al. 2011). In contrast, an initial doubt of necessity for a secondary device inspired active engagement for three recipients (Agard et al., 2007). Conversely, an increasing appreciation of SCD risk, physician recommendation and ICD candidacy was associated with active engagement for others (Yuhas et al., 2012; Carroll et al., 2011). High levels of confidence and trust in physician expertise and recommendation was frequently associated with passive acceptance of advice without further questioning of benefit and risk (Groarke et al., 2012; Lucas, 2012; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011; Matlock et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007). A lack of trust in the physician prompted passive reliance upon well informed family and significant others to support or make the decision (Ottenberg et al., 2014; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011) or they actively declined treatment. Passive decision makers were more likely to defer responsibility entirely to the family and significant others, whereas active decision makers tended to confirm their decision with their family (Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011).

Constraints on available time for information gathering, assimilation and deliberation experienced by some contemplating a secondary ICD may explain forced adoption of a passive style. Hospitalised patients reported brief discussion and little perceived time to absorb, assimilate and understand the implications of treatment (Hauptman et al., 2013; Gal et al., 2011; Agard et al., 2007). Gal et al. (2011) described the event for some as so severe or time limited that it negated the patients potential for agency in decision-making, though it wasn’t clear whether this applied to secondary or primary ICD. Time to deliberate was more readily available for recipients contemplating primary preventative ICD (Ottenberg et al., 2014; Carroll et al., 2011; Al-Khatib et al., 2011) however it is unclear whether this enabled greater engagement in decision-making.

Matlock et al. (2010) described a highly complex set of influencing factors which are magnified among heart failure patients, such as diminished cognitive function, low health literacy and depression which may influence a more passive approach, though links to age were not specified. The level of involvement with decision-making could be related to coping mechanisms (problem focused or avoidant coping), with an association between passive decision-making and passivity in coping with illness (Allman et al., 2009). This was only briefly alluded to by Matlock et al. (2010), who recommend further research to assess control preferences and measure potential predictors of decision style such as coping styles and demographic information.

Sub Theme 1.3 Accepting Or Refusing Device Therapy

Factors that appeared to influence decision style and were cited as reasons to accept or decline device implantation are summarised in Table 2.6.

Table 2-6 Factors Affecting Acceptance Or Refusal Of Device Therapy

Acceptance	Refusal
Current health status considered to be poor. Perceived severity of the condition or undesirable symptoms were a persuasive factor to accept the device in the mistaken belief that it would alleviate symptoms (Lucas, 2012; Gal et al., 2011; Carroll, S. et al., 2011; Matlock, DD. et al., 2011b; Agard et al., 2007)	Focus upon current health status considered to be satisfactory rather than the health trajectory 'if it's not broken don't fix it' and 'don't mess with a good thing', 'my health is good enough' (Ottenberg et al., 2014; Yuhas et al., 2012; Lucas, 2012; Gal et al., 2011; Carroll, S. et al., 2011; Matlock, DD. et al., 2011b; Agard et al., 2007)
Strong belief in medically indicated need for CRMD (Lucas, 2012; Gal et al., 2011; Carroll, S. et al., 2011; Matlock, DD. et al., 2011b; Agard et al., 2007)	Primary prevention candidates denied personal risk of SCD and deemed the ICD unnecessary (Ottenberg et al., 2014; Yuhas et al., 2012; Al-Khatib et al., 2011; Carroll et al., 2011)
Strength of trust in and desire to heed physician recommendation (Groarke et al., 2012; Lucas, 2012; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007)	Perceived the strength of recommendation to be weak (Groarke et al., 2012; Lucas, 2012; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007)
Desire for life prolongation, avoid death (Lucas, 2012; Gal et al., 2011; Carroll, S. et al., 2011; Matlock, DD. et al., 2011b; Agard et al., 2007)	Value quality of life over quantity (Ottenberg et al., 2014; Carroll et al., 2011)
Gender not thought to affect acceptance or refusal but women 2.9 times more likely than men to state 'afraid to die' (*p*=0.003) and given as main reason to accept ICD. 2.4 times more likely to state 'no choice' (*p*=0.01) though 2.3 times less likely to state they 'needed the ICD' than men (Kantor et al., 2012; Gal et al., 2011)	'Accepted their lot' and choosing to live life without invasive life extending treatment (Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011)
Concern and responsibility for and desire to have more time with family (Carroll et al., 2011; Gal et al., 2011; Matlock et al., 2010)	Trade-off between dying quickly over living longer with progressive heart failure (Matlock et al., 2011)
Perceived benefits, 'save my life', 'safety net' and 'life insurance policy' believed to be greater than risk (Gal et al., 2011; Agard et al., 2007).	Believed the burden of the device outweighed the benefit (Singh et al., 2012; Matlock et al., 2011)
Some inaccurate beliefs on lifestyle impact were reported by both acceptors and decliners (Yuhas et al., 2012; Al-Khatib et al., 2011).	Belief that it would impose unwanted restrictions upon lifestyle (Yuhas et al., 2012; Al-Khatib et al., 2011).
	Fear of complications e.g. potential device malfunction, recall, surgical risk (Yuhas et al., 2012; Al-Khatib et al., 2011).
	Advancing age and co-morbidity (Carroll et al., 2011)
	Reported inadequate knowledge (Singh et al., 2012)

The degree of involvement with the decision-making process did not appear to equate to greater acceptance or refusal of device therapy (Carroll et al., 2011). However, current health status, fear of SCD, strength of, trust in and desire to heed physician recommendation, desire for life prolongation versus concern for quality of life and family concerns did (Ottenberg et al., 2014; Lucas, 2012; Groarke et al., 2012; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011; Al-Khatib et al., 2011; Agard et al., 2007).

Sub Theme 1.4 Decisional Outcomes

Four studies considered decision quality and outcome measures (Groarke et al., 2012; Hickman et al 2010 and 2012; Singh, N. et al., 2012; Agard et al., 2007). Singh, N. et al. (2012) reported only 2 (7%) ICD patients would not accept an ICD again, while 18 no ICD (86%) patients stated that they would now reconsider implant ($p<0.001$). 70 of 75 participants (93%) were satisfied with their decision to accept ICD therapy (Groarke et al., 2012) however it was not clear how this was established. The Decisional Regret Scale (DRS) (Brehaut et al., 2003) was used with a convenience sample of 109 ICD recipients, by Hickman (2010) who did not find a significant association between the amount of decision regret (no regret vs. regret) and demographic or clinical variables, such as the ICD indication (primary vs. secondary prevention) or ICD shock status (no shock vs. shock), when adjusted for age, gender and the number of post-decision complications. Similarly, despite being in receipt of insufficient information at the time of implant, Groarke et al., (2012), Singh, N. et al., (2012) and Agard et al., (2007) found little evidence of decision regret. However, informational coping styles, monitoring and blunting, were found to be significant predictors of decision regret, when adjusted for clinical and psychological variables (Hickman, 2010). In 2012, exploratory and confirmatory factor analyses, internal reliability consistency (= 0.86) and discriminant validity established the decision regret scale (DRS) to be a valid and reliable measure of decision regret in ICD recipients (Hickman Jr et al., 2012).

2.3.5 Cluster 2 : Device Knowledge Acquisition And Recall

Sub Theme 2.1 Insight Into Condition, Device Role And Function

Some recipients conveyed a lack of insight about their condition (Singh, N. et al., 2012), the reason for implant (Hauptman et al., 2013; Groarke et al., 2012) and device function and role (Hauptman et al., 2013; Groarke et al., 2012; Lucas, 2012; Carroll et al., 2011; Agard et al., 2007). Singh, N. et al., (2012) compared levels of knowledge among patients who accepted (n=29) and refused (n=21) primary prevention ICD, and discovered a poor understanding of heart failure rated as 4.5 on a scale of 1-10 across both groups. Those who declined an ICD had less understanding of ICD purpose *p*<0.0003, were less likely to have been given written ICD information (71 vs 38%, *p*=0.02), and were less likely to recall a recent discussion on the topic of ICD's (52%) (Singh N. et al., 2012). Groarke et al. (2012) investigated the extent to which 75 device recipients understood the reason for implant and retained information. 62 (83%) patients claimed to understand, however a subgroup of 25 (33%) asked to explain the reason for ICD implant, failed to provide an accurate explanation. No one suggested arrhythmia termination, though 9 (24%) inferred an arrhythmia related reason, 7 (28%) suggested heart failure and 7 (28%) gave various other reasons including reducing risk of ‘heart attack’. 5 (20%) were unable to state a reason at all other than physician recommendation, yet 59 (79%) participants believed they had received sufficient information to consent (Groarke et al., 2012). Similarly on a scale of 1 (not informed at all) to 10 (had all information I wanted or needed), the mean rating of preparedness for 39 patients was 5.7 out of 10 (SD 3.2) at the time of the implant procedure (Hauptman et al., 2013).

Recipients often misunderstood the role and function of device therapy (Chan et al., 2016; Ottenberg et al., 2014; Hauptman et al., 2013; Groarke et al., 2012; Singh, N. et al., 2012; Lucas, 2012; Carroll et al., 2011; Matlock et al., 2011; Agard et al., 2007). Many held inaccurate and optimistic expectations of ICD efficacy including perception that the ICD would relieve symptoms (Groarke et al., 2012; Carroll et al., 2011; Agard et al., 2007), and provide a ‘cure’, until post implant realisation that it would not (Hauptman et al., 2013), suggesting possible minimisation or denial of risk by physicians. Of 69 ICD recipients, 42 (61%) incorrectly believed that the device would improve cardiac function, 36 (52%) breathing, 35 (50%) the ability to exercise, 45 (65%) believed it would reduce the risk of heart attack, or 33 (48%) stopping breathing (Groarke et al., 2012). Patients overestimated its life saving capacity believing that the mean estimated number of patients out of 100 saved by an ICD was 87.9 (SD = 20.1) (Hauptman et al., 2013). Four (13%) secondary ICD recipients falsely credited the ICD with saving their life, relieving symptoms and preventing further cardiac events despite not having received shock therapy (Agard et al., 2007). Older recipients (mean age 84 years) reported having limited information about device role, function and what they may expect. One participant expressed frustration at the lack of information, some felt information was beyond their comprehension and most failed to seek additional information (Lucas, 2012). Patients identified gaps in their learning about ICD role and function, yet many believed they had received sufficient information to consent (Hauptman et al., 2013; Groarke et al., 2012). Clinicians appeared unaware of the apparent lack of knowledge (Ottenberg et al., 2014).

Sub Theme 2.2 Physician Communication And Information Received

There appeared to be a focus upon the ‘benefit bias’ presented in published guidelines. Observed CRMD consultations reported inadequate information giving and a tendency for physicians to focus on the medical procedure, with knowledge of risk only becoming apparent when experienced post implant (Hauptman et al., 2013; Al-Khatib et al., 2011; Agard et al., 2007). Some patients indicated little interest in detailed knowledge of risks (Hauptman et al., 2013). Unexplained medical jargon was often used and there was a primary emphasis upon prevention of SCD whereas study data of the prevalence of actual life-saving shock therapy, the number who require shock therapy, or the risk of death despite shock therapy was rarely included (Hauptman et al., 2013; Agard et al., 2007).

Some recipients identified potential peri-procedural complications including infection (43-57%), bleeding (22-29%), infection requiring device removal (20-27%), pneumothorax (12-16%) and lead perforation (18-24%). Whereas, other recipients were not aware and could not recall receiving such information (Groarke et al., 2012). Hauptman et al. (2013) also reported infection (10-45%) and bleeding (11-50%) as most often noted with less emphasis upon major risks such as pneumothorax or lead dislodgement. Similarly, 33 of 41 recipients (80%) denied discussion of post implant complications such as lead displacement, ICD recall or inappropriate shock (Hauptman et al., 2013; Groarke et al., 2012; Lucas, 2012; Matlock et al., 2011; Agard et al., 2007). 20 patients experienced shock therapy, though 12 (60%) felt inadequately prepared and of 12 patients who experienced other device complications, 10 (83%) reported feeling insufficiently forewarned (Groarke et al., 2012). Inappropriate shock was discussed in 15 (68%) interviews, though the risk was minimised in 11 of 15 cases (Hauptman et al., 2013). Patient’s reported infrequent reference to possible psychosocial outcomes including anxiety, depression or quality of life issues, other than social concerns such as security devices (Hauptman et al., 2013). Observation of 22 consultations confirmed that the risk of anxiety was mentioned in one third of interviews and depression not mentioned at all (Hauptman et al., 2013). An emphasis on ICD as the only option, with minimal recall of any discussion of alternatives, such as drug therapy or ablation existed (Carroll et al., 2011; Agard et al., 2007).

The use of decision aids did not feature in the ICD studies with the exception of Hazelton et al (2014) who designed and tested a 22 item, two factor subscale of pros and cons (ICD Decision Analysis Scale ICD – DAS), to assist decision-making on 104 prospective ICD recipients. They based their research upon the premise that patients who are given the opportunity to process pros and cons and are involved in treatment decisions, report increased satisfaction, reduced decisional conflict and greater compliance with treatment. Hazelton et al. (2014) reported that 75% of respondents rated improved mortality, longevity, quality of life and Dr’s recommendation as extremely or very important factors which influenced their ICD decision. Most other items were considered to be relatively important. 50% rated 3 specific items, such as faith, scar and receiving a shock when around other people, as not or slightly important.

The total scale was found to have high internal consistency (Cronbach’s alpha 0.92), 0.88 for the pros scale and 0.91 for the cons scale. A greater percentage of overall variance was demonstrated by the ICD cons subscale, consistent with research indicating that most patients are more affected by risks than benefits. Other general psychosocial measures included in the study (MOS SF-12; HAD; C-MHLC scales) were not significantly predictive of ICD choice, leading the researchers to conclude that the ICD-DAS was a more efficient and accurate predictor of patient intent to choose the ICD. Hazelton et al. (2014) recommended use of the scale in practice to facilitate information exchange and deeper discussion of patients knowledge, understanding and preferences for an ICD. However, the study to develop and test the decision aid specific to ICD (Hazelton et al., 2014) was based upon a relatively small sample of clinic patients and may not be entirely representative. A pilot study to develop and test a decision aid, designed to support patients contemplating primary prophylaxis ICD implantation is currently underway (Carroll et al., 2013).

The inclusion of a review within a review would generally be unexpected. However, the integrative review by Lewis et al. (2014a) fulfilled the scoping inclusion criteria and was therefore retrieved for completeness. The primary studies (n=14) were initially summarised and appraised independently, prior to any consideration of Lewis et al. (2014a). The integrative review by Lewis et al. (2014a) focused upon patient experience of decision-making from implant, to battery or device replacement and deactivation at the end of life and was therefore concerned with the trajectory of decision-making over time rather than focus upon the implant stage, as in this review. The review of initial implant decision studies featured eight (Hauptman et al., 2013; Kantor et al., 2012; Groarke et al., 2012; Yuhas et al., 2012; Carroll et al., 2011; Matlock et al., 2010 & 2011, Agard et al., 2007) of the fourteen studies included in this review. Lewis et al. (2014a) described three emergent themes which correspond with Clusters 1 and 2 of this review. ‘Types Of Decision-making Preferences’ which referred to the adoption of active processes of information gathering and passive deferral of decision-making were also represented here in Cluster 1, sub-theme 1.1. Factors influencing the decision style were only alluded to by Lewis et al, but considered in more detail in Cluster 1, sub-theme 1.2 of this review. A second theme described by Lewis et al. (2014a) as ‘The Will To Live’, was characterised by the impact of initial fear and uncertainty associated with realisation of potential sudden cardiac death and the balance of benefit and risk upon acceptance or refusal of device therapy, which was similarly portrayed in Cluster 1, sub-theme 1.3. This review presents factors associated with acceptance and refusal of ICD in greater detail than Lewis et al. (2014). The third theme emerging from the integrative review was ‘Influence Of Patient - Practitioner Consultation’ (Lewis et al., 2014a) This theme cited concerns with information receipt and recall, knowledge and misconception of role, function and overestimation of benefits and available time to deliberate, reflecting findings described in Cluster 2. Lewis et al. (2014a) also make reference to seven other studies concerned primarily with knowledge related to deactivation and end of life issues which were not included in this review. Further distinctions include reference in this review to six other studies (Ottenberg et al. 2014; Hazelton et al. 2014; Lucas 2012; Singh, N. et al. 2012; Gal et al. 2011; Hickman et al. 2010 & 2012), and consideration of decision aids and decision outcomes (sub-theme 1.4) which were not featured in Lewis’s integrative review. The distinction in focus, yet commonalities in thematic interpretation established between Lewis et al. (2014a) and this review substantiated the analytical approach taken and enhanced strength and credibility of the analysis and interpretation of current knowledge. For this reason it was considered to be worthy of inclusion within this thesis.

2.4 Discussion

2.4.1 Consideration Of The Meaning Of The Results In The Broader Context

It was sometimes difficult to ascertain whether findings applied specifically to patients who had primary, secondary, ICD or CRT devices. The significant influence of indication and device type upon the pre-implant experience, patient perception of need and potential outcomes may have an important impact upon decision-making. Secondary devices assume recovery from SCA, whereas primary devices do not. Furthermore, unlike ICD therapy designed only to prevent sudden arrhythmic death, the CRT may also provide symptom relief for some heart failure patients, which may inform and promote decision-making. Also, the trajectory of illness, pre-implant experience, indication for, and available decision-making time prior to ICD implantation differs significantly between secondary and primary prevention, prompting the need for a more focused investigative approach upon one group. For secondary recipients, the predicted balance of benefit over risk is relatively well established and the perception of ‘no choice’ and little time to deliberate appears more likely to precipitate passivity, increasing the potential to lack understanding of the implications of device therapy. This group warrant further investigation, however patients may be more difficult to capture, as they are routinely transferred to a district home unit for follow up within 12 hours post implant and therefore will not feature further in this thesis.

The balance of benefit and risk is less clear for primary prevention recipients. Those with LV dysfunction (EF<35%) of an ischaemic aetiology have an approximate 10% relative SCD risk without a device but have a 27-30% 2 year reduction in mortality with ICD (Ragupathi and Pavri, 2014). Whereas, those with a non-ischaemic aetiology may have a lower SCD risk (but higher than age matched adults) without a device, but stand to gain a 40-80% reduction in mortality risk with ICD (Kadish et al., 2004). However, the latter group tend to be younger, are less likely to ever experience device therapy and yet, are at risk of device complications due to the increased years of implantation. The balance between not treating and risking a preventable arrhythmic event, and the inevitable cost and complications associated with implantation for lower risk groups, is therefore much less clear for primary recipients. Additionally, a predictive risk stratification for each group of conditions is not well established in the literature (NICE, 2014).

The decision approach may influence information exchange. While SDM and collaborative styles are key topics in the decision-making literature (Shay and Lafata, 2015; Joseph-Williams et al., 2014; Elwyn et al., 2014; Katz, S. et al., 2014; Légaré et al., 2014; Couet et al., 2013; Tariman et al., 2012; Elwyn et al., 2012), the level of SDM in cardiology consultations is not well known (Langseth et al., 2012). Only one CRMD study alluded to patient perception of joint decision-making (Groarke et al., 2012). In contrast to the preference for SDM in the general literature (Flierler et al., 2013; Tariman et al., 2012; Singh, J. et al., 2010) reference to distinct passive and active approaches, dominated the CRMD studies. The majority of ICD patients desired passive involvement, echoing findings among general cardiology patients (Burton et al., 2010). Rapid, intuitive referral to the ‘expert opinion heuristic’ and passive deferral of decision-making responsibility to the physician, was evident among secondary device recipients. Although paternalistic, and criticised for failing to embrace patient-centeredness, and the fundamental centrality of autonomy and beneficence required for informed consent (Department Of Health, 2010b; Coulter, 1999; Charles et al., 1999), this approach could be appropriate in the context of post SCA secondary prevention where the benefit risk ratio is well established (Connolly et al., 2000). Recovery from the traumatic event, symptom severity and treatment complexity, limited time to deliberate, feeling ill equipped to make a choice and high levels of trust in physician expertise, evident in the CRMD studies are factors widely associated with passivity in the decision literature (Puts et al., 2015; Ernst et al., 2013; Song et al., 2013; Frosch et al., 2012; Loeffert et al., 2010; Say et al., 2006). This approach may assure acceptance on the basis of clinical need, however patients may fail to sufficiently consider the benefits and potential harms of life changing device therapy, casting doubt upon the extent to which autonomous, informed consent has been reached.

Passivity was also described among patients contemplating primary prophylactic devices (Chan et al., 2016; Carroll et al., 2011; Matlock et al., 2011; Matlock et al., 2010) when symptoms may be absent, suggesting that more deliberation time may not increase engagement in decision-making. The clarity of perceived benefit and risk for primary devices may be a factor. The risk of life threatening arrhythmia and survival benefit afforded by the device, in the presence of ischaemic aetiology or certain heart failure characteristics is well known (Goldenberg et al., 2010; Bardy et al., 2005; Moss et al., 2002). Therefore, reference to clinical guidelines for CRMD implantation, particularly when framed as essential rather than optional (Yuhas et al., 2012; Gal et al., 2011), may present an air of confidence which promotes patient trust in physician recommendation, and consequent passive acceptance of device therapy. It may not however guarantee ‘informed’ consent. Conversely, the predictive risk stratification of inherited cardiac conditions is less established, therefore a lack of standardised information may lead to poorer patient understanding, and diminished confidence in the physician and perceived strength of recommendation, which may explain subsequent passive reliance upon significant others to decide (Yuhas et al., 2012; Gal et al., 2011; Carroll et al., 2011) or refusal of therapy (Carroll et al., 2011). Ultimately, an explicit link between passivity, poorer knowledge and understanding described by the CRMD studies is problematic (Chan et al., 2016; Lucas, 2012; Carroll et al., 2011; Agard et al., 2007).

In contrast, independent information gathering and leaving the ultimate treatment decision exclusively to CRMD patients, presupposes high levels of health literacy and cognitive ability, that they are truly autonomous, that their information needs, values and preferences are known, and they are certain of their wishes (Charles et al., 1999). The source of the information is also a concern as the reliability and confidence in information acquired from ‘non-expert’ sources, such as family, friends and media avenues has been described as ‘highly variable’ (Bruce et al., 2015; King-Shier et al., 2013; Fagerlin et al., 2006). This may explain the lack of accurate knowledge also found among ‘active information seeking’ device recipients (Ottenberg et al., 2014).

Moreover, expression and interpretation of patient preferences and values, based upon subconscious intuitive judgement processes may challenge decision-making. For instance, referral to past experiences or anecdotal experiences of others, known as the ‘availability heuristic’ (Kahneman, 2011; Gigerenzer and Todd, 1999); thought to motivate some patients to accept or decline therapies (Puts et al., 2015; Mead et al., 2013), was acknowledged among CRMD patients (Chan et al., 2016; Ottenberg et al., 2014; Matlock et al., 2011). This may be relevant as the exact mechanism of heuristic based treatment decision-making is not clear in the general literature, however the potential bias effect upon decision-making has been demonstrated (Martinez, K. et al., 2015; Brom et al., 2014; Chewning et al., 2012; Kahneman, 2011; Lam et al., 2005; Chaiken and Maheswaran, 1994). Individuals could be induced to make sub-optimal decisions based upon positive or negative events that contradict physician advice (Chan et al., 2016). For example, third-hand knowledge of shock experience or device related complications may present sufficient anticipation of adverse events, to deter some who would benefit from acceptance, presenting a negative availability heuristic. In contrast, risk aversion may exaggerate patient preference for more invasive treatments, whereby the presence of a small but above average risk of SCA, may unnecessarily provoke patients to request the highest end technology available.

The notion of systematic and non-systematic approaches to information processing was implied rather than explicit in the ICD studies. It is not clear whether one or a combination approach leads to the most satisfactory outcome and ICD recipients appear to differ in the degree to which they engage in information processing. There was an implicit suggestion that information gathering was synonymous with active engagement, and reliance upon heuristic processing with passive deferral, within the ICD studies. Actively engaged ICD recipients appeared to gather information in a systematic manner, however despite the potential to have a significant impact upon the decision, the degree to which these patients referred to heuristic processes was much less explicit and not explored in detail. It was therefore difficult to determine exactly what inspired some individuals to adopt an active stance or what influence heuristic (if this occurs) thinking had upon decisions. Given the complexity of decision-making, it may be unlikely that ICD patients rely solely upon one approach. The degree to which primary CRMD recipients refer to systematic information gathering and heuristic processes merits further investigation as the literature is not clear.

Collaborative decision-making acknowledges an inferred imbalance in medical knowledge and social power between patient and physician, by allowing each to lead different aspects of the discussion, capturing the notion of negotiated responsibility, mutual participation and cooperation rather than emphasis upon shared choice (Politi and Street, 2011; O'Grady L and A., 2010; Schaufel et al., 2009; Makoul and Clayman, 2006; Flynn et al., 2006). The desire for information exchange and deliberation expressed by some CRMD patients, while relinquishing responsibility for the final decision to physician expertise (Carroll et al., 2011) was an indicator of active involvement in collaborative decision-making, and may paradoxically represent a degree of autonomy (Beaver et al., 2009; Deber et al., 2007; Flynn et al., 2006; Kiesler and Auerbach, 2006). Conversely, device recipients who described making active decisions based upon their preferences, while acknowledging physician guidance was similarly described in previous cancer studies (Slot and Berge, 2009; Cox et al., 2006). Greater emphasis upon collaborative CRMD decision-making may facilitate improved knowledge acquisition and foster inclusion of personal preference, which is valued and perceived as greater involvement in decision-making by patients (Holmes-Rovner et al., 2015; Kunneman et al., 2015; Joseph-Williams et al., 2014; Mulley et al., 2012).

Systematic reviews of patient preference for involvement in decision-making revealed considerable variation dependent upon disease type, severity and progression and while the majority preferred a collaborative approach (probably more firmly embedded in cancer care than other specialities), a significant minority favour a passive style (with little or no detailed information or involvement in the decision), and few a more active approach (Singh, J. et al., 2010; Hubbard et al., 2008; Kiesler and Auerbach, 2006; Say et al., 2006; Gaston and Mitchell, 2005). This pattern was not clearly reflected in the ICD studies (Table 2.7). Groarke et al. (2012) did report preference for a joint decision among some and compared levels of desired and actual participation, however further analysis of the exact nature and extent of different interactions was not expanded upon.

Table 2-7 Match Between Desired And Actual Level Of Involvement

n : %	Meta-analysis - 6 Cancer Studies Singh, J. et al. (2010)		Matlock et al. (2010)	Groarke et al. (2012)	
	Desire	Actual	Actual	Desire	Actual
Traditional passive paternalistic model	872 : 25%	1257 : 36%	10 : 45%	40 : 53%	35 : 47%
Shared decision-making (SDM)	1711 : 49%	1187 : 34%			21: 28%
Active informed (patient) model	908 : 26%	1047 : 30%	12 : 55%	35 : 47%	19 : 25%
Total	3491 : 100%		22 : 100%	75 : 100%	

This may be relevant as cancer studies have reported a significant association between achieving or exceeding the desired level of participation and satisfaction with the consultation, less decisional conflict, regret, less depression and greater overall satisfaction with the decision process regardless of the treatment choice (Brown et al., 2012; Anderson et al., 2009; Edwards, Adrian and Elwyn, 2006; Kiesler and Auerbach, 2006; Keating et al., 2002). It may not be the actual participatory style but rather the match between the physician's interactive style and the patient's desired level of information and participatory preference for deliberation and final decision-making which matters (Gaston and Mitchell, 2005; Guadagnoli and Ward, 1998). Therefore, rather than a forced emphasis upon adoption of SDM, adherence to the patient's preferred style of participation may be more appropriate. Although Groarke et al. (2012) considered the match between desired and actual involvement in ICD decision-making their methods of data collection and analysis were not reported.

Although decision approach did not appear to influence device acceptance (Carroll et al., 2011), inadequate knowledge was associated with device refusal (Chan et al., 2016; Singh, N. et al., 2012) and dissatisfaction (Lucas, 2012). An association between increasing age, passivity and poor knowledge acquisition described in the general decision literature (Chung et al., 2012; Ernst et al., 2011) was apparent among older adults contemplating device therapy (Hauptman et al., 2013; Lucas, 2012), however generalisation is limited by the small cohort size. Further focused investigation into the impact of complex factors associated with older age and potentially exacerbated in heart failure and post SCA, such as diminished cognitive function, low health literacy, numeracy and depression (Malloy-Weir et al., 2015; Smith, S. et al., 2009; Allen et al., 2008; Bekelman et al., 2007; Dickson et al., 2007; Rutledge et al., 2006; Fagerlin et al., 2006), is warranted if support strategies to meet specific needs are to be developed. There was little mention of potential gender differences in the CRMD studies (Kantor et al., 2012; Gal et al., 2011), though the tendency for women towards active engagement compares with other findings (Chung et al., 2012; Say et al., 2006; Flynn et al., 2006; Gaston and Mitchell, 2005). Other factors influencing acceptance or refusal such as condition severity and perception of necessity, strength of, trust in and desire to heed the recommendation and the trade-off between longevity and QOL, corresponds with cancer treatment decision-making (Puts et al., 2015). Consistent with the general treatment literature (Puts et al., 2015) there is limited information regarding the influence of culture, ethnicity and other potential demographic differences in the CRMD studies. Device type presents some indication of condition and symptom severity yet it was sometimes difficult to determine whether study findings referred to primary or secondary prevention devices. In addition, unlike ICD device therapy alone, biventricular pacing may represent an improvement in heart failure symptoms for some and as such offers an additional incentive to choose device therapy which may influence decision-making. Studies to date have not focused specifically upon the initial thoughts of patients with heart failure faced with a recommendation for CRT, therefore more focused investigative approach which clearly delineates device type is warranted.

The level of involvement with decision-making could be related to coping mechanisms (problem focused or avoidant coping), with an association between passive decision-making and passivity in coping with illness (Allman et al., 2009), though this was only briefly alluded to by Matlock et al. (2010). A range of cognitive, behavioural and emotional coping responses to stress have been described, such as problem versus emotion focused coping (Folkman and Lazarus, 1980), task versus emotion versus avoidant oriented (Endler and Parker, 1994), vigilance and cognitive avoidance (Krohne, 1996; Krohne, 1993), and the theory of monitoring and blunting (Miller, 1995; Miller, 1980). ‘Monitoring’ refers to either ‘active information seeking’ or ‘sensory vigilance’ (Miller, 1981) which reflects problem focused coping. ‘Blunting’ manifests as complete avoidance or partial distraction incorporating various behavioural and cognitive strategies (Parker, J. and Endler, 1992; Miller, 1981), and reflects emotion focused coping (Folkman and Lazarus, 1980). A review of cancer studies revealed a potential association between monitoring and blunting coping, decision style and decision outcome (Roussi and Miller, 2014; Sie et al., 2013; Timmermans et al., 2007; Ong et al., 1999). High monitoring was found to be positively associated with increased desire and gathering of detailed health relevant information, especially in the face of ambiguous threat (Rood et al., 2015; Sie et al., 2013; Wakefield et al., 2007; Ong et al., 1999). Monitoring was said to be concerned with sufficiency and level of satisfaction with information, and the nature of the interaction between physician and patient (Roussi and Miller, 2014; Timmermans et al., 2007; Ong et al., 1999). Therefore, communication between physician and patient which focuses upon factual content such as condition and available alternatives, information exchange including patient values and preferences, and an affective element linked to the emotional experience of the interaction is central to this (Roussi and Miller, 2014). Monitoring was also associated with more active involvement in cancer treatment decision-making (Rood et al., 2015; Timmermans et al., 2007; Wakefield et al., 2007; Ong et al., 1999). Anderson et al. (2009) suggest that women with breast cancer who prefer a passive role or who avoid active participation in order to evade having to evaluate trade-offs of different options, and the associated negative emotions, may have a tendency to adopt avoidant coping strategies which in turn may negatively affect adjustment and HRQL (Anderson et al 2009). Conversely, patients who engaged in problem focused coping reported lower levels of anxiety and depression and better HRQL (Anderson et al., 2009). Miller et al. (2005) had suggested a link between high monitoring, overestimation of perceived risk related to greater focus upon impending threats, and therefore greater anxiety though others did not identify a significant relationship (Wakefield et al., 2007). Yet monitors were more likely to doubt choices, report decisional conflict (Sie et al., 2013), dissatisfaction with information received and decisional regret, and as a consequence remain focused upon alternative options rather than acceptance of the decision choice (Timmermans et al., 2007). It therefore remains unclear whether engaging in high or low monitoring affords more or less advantage, in the context of difficult healthcare decisions bound by high levels of threat and ambiguity. Matlock et al., (2010) proposed a potential association between passive decision-making and deeper constructs of passivity in coping with illness and recommend further exploration to determine whether or to what extent, monitoring coping styles might affect and may predict patient's decision-making. Hickman (2010) also concluded that informational monitoring and blunting coping styles may predict decision regret.

Empowering patients to exercise their autonomous right to informed consent, achieving decisional satisfaction and avoidance of cognitive dissonance, conflict and regret are evidence of effective patient decision-making. Decisional satisfaction and regret were referred to by Groarke et al., (2012), Singh, N. et al., (2012) and Agard et al., (2007) though standardised measures were not used to collect data in these studies. Hickman et al (2012 and 2010) did acknowledge the value of, and used the pre-validated Decisional Regret Scale (DRS) (Brehaut et al., 2003) with ICD recipients, but they didn't include analysis of decision regret among decliners or consider indication or device type. Thus, emphasis upon decision outcomes within the scoping studies was the least well represented among the studies and may benefit from further investigation.

The widespread lack of knowledge and understanding of condition, device role, risks and alternative options across the CRMD studies is a concern and echo's widespread misunderstanding of the extent of disease, prognosis, aim of treatment and alternative supportive care, reported in a systematic review of information receipt in advanced cancer (Gaston and Mitchell, 2005). Several reasons have been proposed in the research, including lack of information, insufficient time, consultation style, misguided therapeutic privilege to protect the patient from bad news and loss of hope, or problems associated with stress related memory recall or rejection, as part of the denial element of coping behaviour (Gaston and Mitchell, 2005). Reported inaccuracies in this review may have been a function of the time between implant and data collection (1 to 16 years) on retention and recall of information. However, interviews one month post implant by Carroll et al. (2011) revealed similar findings, suggesting that the gravity of the situation may have affected what recipients hear, recall and a focus upon survival information. Age, cognitive and emotional barriers, communication deficits, situation seriousness, individual experience and variation in the desired amount and type of device information, may impact upon patient perception of information or even reduce the relevance of some facts (Hauptman et al., 2013; Polacek et al., 2007; de Haes, 2006; Fagerlin et al., 2006).

Clearly, misinformation and misunderstanding may lead to uninformed consent. Much of the emphasis in the literature is upon strategies to educate patients to cope with and manage chronic conditions through lifestyle behaviour change. The importance of tailoring health information to individual socio-demographic characteristics and manipulation of message content and format is well established (O'Keefe, 2013; Gallagher and Updegraff, 2012). The benefits in terms of anxiety and satisfaction with tailored information, not only relies upon individual cognition required to perceive and process health information, but matching messages to patient preference (Vosbergen et al., 2013; Kiesler and Auerbach, 2006). Vosbergen et al. (2013) made a connection between patient preferences for various message formats, levels of health literacy and monitor-blunter coping style.

The World Health Organisation (WHO) defined health literacy as the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make health-related decisions (World Health Organisation, WHO., 2013). It is an important attribute but one which is not merely an inherent trait or the sole responsibility of the individual. Society and the healthcare service have an obligation to empower people to take control of their health, seek out relevant, appropriate information and so make informed choices (Berry, J., 2016). In England, common healthcare materials were considered to be at the literacy level expected to be achieved by 14 to 16 year old students (NVQ level 2) and a numeracy level suitable for 11 to 14 year old students (NVQ 1) (Rowlands et al., 2013). Yet the European prevalence of low level health literacy is approximately 50% (HLS-EU, 2012). Several factors are known to contribute to low level health literacy including living in the North East England, older age, BME groups, level of formal education, low grade employment and income (Rowlands et al., 2013). Monitor-blunter coping style describes the way an individual copes with personally threatening information (Miller, 1987). Vosbergen et al. (2014) subsequently concluded that variation in individual preferences for certain information formats was influenced by socio-demographic characteristics including age, marital status, social support and condition, as well as health literacy level and monitor-blunter coping style.

The ICD studies reviewed referred predominantly to patient–physician information exchange whereas many implant centres now adopt a multi professional approach. Focus upon benefit bias and procedural issues, rather than psycho-social outcomes and quality of life resembles other studies, which reveal differences in physician priority on survival and longevity over patients preference for preservation of quality of life (Caverly et al., 2012; Zikmund-Fisher et al., 2010b; Cox et al., 2006; Feldman-Stewart and Brundage, 2004). In a multi-centre Danish survey, physicians reported greater emphasis upon the clinical aspects and procedural risks of ICD implantation, and focus upon advantages at the expense of disadvantages of treatment, than non-physicians (Johansen et al., 2011). This was reflected in a recent systematic review that concluded that most patients, regardless of intervention type overestimated benefit and underestimated harm (Hoffmann and Del Mar, 2015). Thus, there is a need for comprehensible, predictive information regarding benefits and risks to augment realistic expectations and informed choices (Hoffmann and Del Mar, 2015; Montgomery, 2015). However, physician recommendations are made on increasingly complex clinical evidence which is indication and device specific, and reliant upon contemporary expert knowledge which may influence the degree of importance assigned to clinical matters. It may also challenge the ability of the physician to accurately gauge what, and how much information a patient wants and how to present it in a clear, understandable way, relevant to the patient’s clinical need and capacity to assimilate and comprehend it. Furthermore, physicians spend significantly less time with ICD recipients prior to implantation than non-physicians, limiting the opportunity to consider the emotional impact (Johansen et al., 2011). In contrast, non-physicians reported a greater emphasis upon psycho-social and quality of life concerns (Johansen et al., 2011). Thus, increased involvement of cardiac specialist nurses, clinical physiologists and psychologists and the development of more reliable patient websites to reinforce and complement physician information may improve this (Lewis et al., 2014a).

Decision aids (DA’s) designed to support preference sensitive decision-making, improve understanding, enhance concordance between values and choice and reduce decisional conflict have become increasingly popular in the literature (Stacey et al., 2014; Elwyn, Glyn et al., 2013; Matlock et al., 2012; O'Connor et al., 2009; Leatherman and Warrick, 2008). However, thus far they have not been fully implemented in general practice (Holmes-Rovner et al., 2015; Elwyn, G. et al., 2013) or in the context of CRMD uptake. Development and testing of ICD specific decision aids are currently underway (Carroll et al., 2014; Hazelton et al., 2014) though not thought to be used in practice locally, therefore informal observation of consultation clinics to establish the nature of patient physician interaction and information exchange would be beneficial.

2.4.2 Limitations Of The Scoping Review

Although the small number of studies included in the review could be considered a limitation, the reviewers were confident that a thorough and comprehensive search was undertaken. Unlike systematic reviews or narrative analysis of qualitative studies with similar methodological approaches, scoping reviews by their very nature incorporate a range of published materials, study designs and mixed methods and so the presenting challenge of attempting to summarise, interpret and synthesise the complex and often large volume of diverse data cannot be under estimated. Furthermore, qualitative content analysis in this context assumes a degree of interpretation of findings emerging from several studies, which have already been subject to researcher analysis and interpretation. The danger of dilution of interpretation of original data and the potential loss of some important findings is therefore real. Equally, with open and honest transparency in the way this secondary analysis is conducted the potential to strengthen the findings through assimilation from multiple studies is evident. Therefore, in an effort to maintain hermeneutic consistency, similar language was deliberately adopted to explain, develop, strengthen or refute the significance of key themes and ideas emerging from the original analyses. Finally, although there is some similarity in the scoping review presented here with the integrative review by Lewis et al. (2014a), the latter was interested in the trajectory of decision-making from implant, to battery replacement and deactivation at the end of life, and therefore presented breadth as much as depth of detail. As such, Lewis et al. (2014a) only include eight of the fourteen studies featured here, which was concerned with decision to implant only and therefore aimed to present more depth and detailed understanding of this particular phase. Lewis also applied the MMAT quality appraisal tool to their studies adding further weight to its application in this review.

2.4.3 Concluding Summary And Gaps In Knowledge

This scoping review represents an important contribution to the assessment of the state of academic interest in this field. It has generated some insight in to the way patients approach decision-making related to CRMD recommendation and identified similarities and distinctions with the general treatment decision-making literature. It has also exposed a lack of clarity and research activity specific to patients decision-making regarding primary prevention device therapy in the UK. The following recommendations for further research emerging from the scoping review informed the second phase of this PhD.

The review has demonstrated scope for an examination of relationships among a range of factors that may influence patient choices. A particular focus upon demographic difference (age, gender, marital status, social support, educational level or health literacy) and situational context (perceived severity of illness, symptoms and appreciation of personal risk, device indication and type, decision style and preference for participation) upon levels of knowledge, device acceptance or refusal and decision outcomes was not well established in the ICD studies, and warrants further investigation. Though six studies in the review included mixed race, the majority of participants were indigenous white, leaving the voice of the under-represented largely unheard, highlighting the need to explore decision-making among British white, black and minority ethnic (BME) groups. Comparison of the perspective of those who accept and decline would provide a broader insight of the experience.

Although an association between coping styles and decision-making has been described in the cancer literature, coping as a potential influencing factor was not considered in the ICD studies. Matlock et al., (2010) proposed a potential association between passive decision-making and deeper constructs of passivity in coping with illness and recommend research to measure potential predictors of decision-making style such as coping style to determine how they may be associated with patient's decision-making styles. Hickman (2010) concluded that informational coping styles, monitoring and blunting, may predict decision regret. In light of the gap in knowledge, particular attention to the potential impact and predictive nature of monitoring and blunting as manifest coping strategies upon decision approach, device acceptance and decisional outcome among patients recommended for primary preventative CRMD is recommended. Further analysis of the impact of anxiety and depression upon decision-making is also required. However, for the purpose of this study the addition of yet more validated scales to measure anxiety and / or depression was rejected, on the basis of the extra responder time and the onerous effort it would require. On subsequent reflection, this was an unfortunate decision.

The trade-off between benefit and harm required during ICD decision-making is complicated and the patient perspective a crucial aspect of the process. Therefore, it is necessary to develop a deeper, subjective understanding of the individual and collective process of decision-making from a UK patient perspective, to better inform the development of supportive mechanisms to assist patient decision-making. Specifically, insight in to what inspires active engagement, the degree and influence of heuristic thinking and the appropriateness of SDM for patients contemplating CRMD is advocated. The desired and actual levels of involvement and specifically the potential impact of a mismatch upon decision outcomes also require consideration. Although decisional satisfaction and avoidance of cognitive dissonance and regret are evidence of effective patient decision-making, measures of decision outcome such as decisional control preference, conflict, satisfaction or regret (except Hickman et al. 2012 and 2010), was limited in the literature and recommended for future research.

As the consistency, ambiguity, sufficiency, adequacy and manner of information exchange is central to the decision-making process, and yet apparently variable in practice, further evaluation of the patient-professional interaction particularly in the context of multidisciplinary involvement, time to deliberate, health literacy and levels of patient knowledge is warranted. Development and testing of ICD specific decision aids are currently underway (Carroll et al., 2014; Hazelton et al., 2014) though not thought to be used in practice locally, therefore informal observation of consultation clinics to establish the nature of patient physician interaction and information exchange would be beneficial.

From a methodological perspective, the use of valid outcome measures to assess levels of monitoring, decisional control preference and concordance, conflict, satisfaction and regret are scarce in the literature and warrant greater inclusion in future studies. Lastly, retrospective data collection ranged from 1 to 16 years post implant in all but Carroll et al., (2011) study, which may also have affected memory and allowed other influences such as device therapy to affect recall, therefore the next study phase will examine the decision-making process within a more judicious timeframe.

Chapter 3 converts what is known about patient decision-making for CRMD gathered from the scoping review, in to a conceptual map which provides the basis for the next stage of empirical inquiry. The gaps in knowledge emerging from the literature are transformed in to clear and achievable research aims and objectives to guide the study. Finally the justification for the methodological approach selected to undertake the study is discussed.

2.5 Stage 6 - Consultation

Patient and public involvement (PPI) was considered to be important in capturing alternative perspectives and experiential insight thus potentially adding currency, depth and enhancing the methodological rigour of this study (Levac et al., 2010; Arksey and O'Malley, 2005). Gratitude for the invaluable content expertise, personal perspectives, validation of preliminary findings and recommendations for further research contributed by a group of three CRMD recipients is acknowledged.

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Chapter 3
Research Aims, Theoretical Framework, Philosophical Assumptions And Methodology

3.1 Introduction

The scoping review presented in chapter 2 informed the next empirical phase of this PhD thesis. The scoping review identified a lack of research related to patient decision-making for primary prevention CRMD in the UK. It emphasised the need for the exploration of a range of issues that may influence how adult patients reach a decision to accept or decline cardiac devices. In particular, the voice of British white, black and minority ethnic (BME) patients thus far under-represented in the literature required inclusion in future studies. Additionally, the need for further examination of a range of important, potentially predictive factors (demographic characteristics, situational context, patterns of coping, desired level of involvement, information exchange, physician interaction), which may influence the adopted approach, levels of knowledge, the decision to accept or decline therapy and decisional regret, among UK patients was highlighted. A particular area of interest arising from the scoping review was a potential, but unknown relationship between informational coping styles, patient's decision-making styles and decision regret. Therefore, focus upon assessment of monitoring as an informational coping style featured within this thesis.

A concurrent exploration of the patients subjective experience, to establish a deeper understanding of how patients approach decision-making, and to generate themes about the internal and collective decision-making processes employed was also considered to be important. As the acquisition and assimilation of knowledge to inform consent is central to effective decision-making, further evaluation of the patient-professional interaction particularly in the context of multidisciplinary involvement, health literacy and levels of patient knowledge was also warranted. Finally, to address some of the methodological issues raised in the scoping review, the next study phase made use of valid outcome measures to examine the decision-making process within a more judicious timeframe. This chapter considers the research aims and discusses the theoretical basis and methodology that underpins the empirical phases of research.

3.2 Research Aims

As presented in Chapter 1, the overarching research question for this thesis was;

> **‘What influences adult patients' decision-making in accepting or declining primary prevention complex cardiac rhythm management devices (CRMD)?’**

Three clear and achievable study aims were designed to facilitate the research design, and maintain focus and direction for the next phases of the thesis;

Aim 1:

> To determine whether an association exists between existing socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret

Aim 2:

> To develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed

Aim 3:

> To examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

3.3 Research Rationale

The predominant rationale for undertaking this research was;

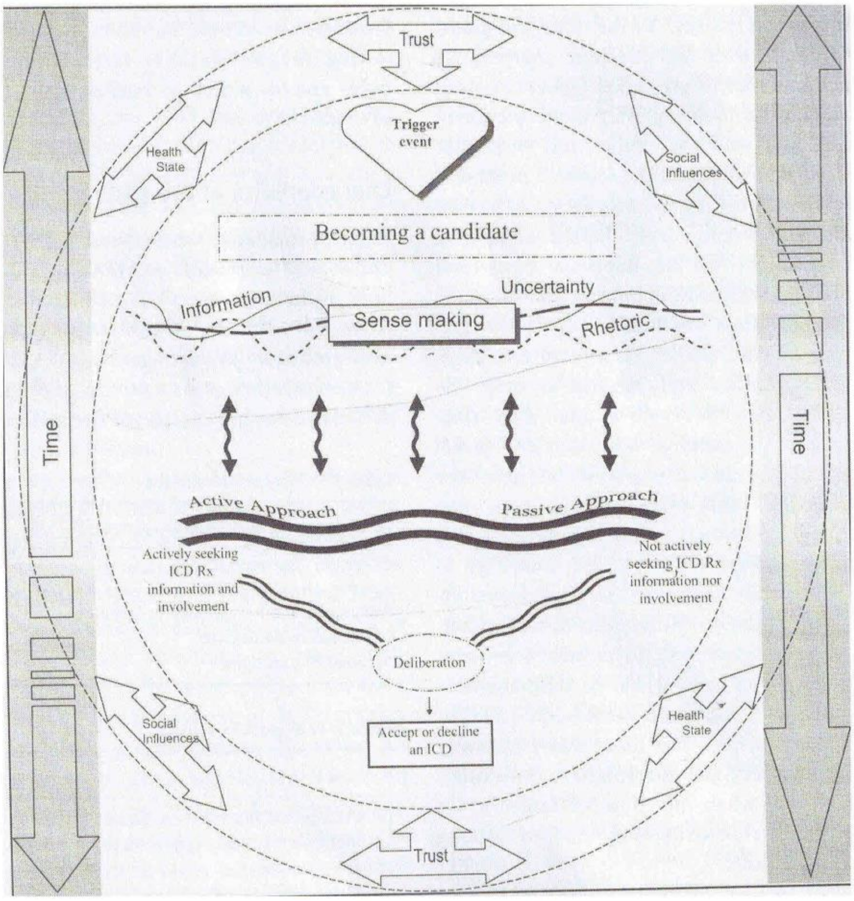
> ‘*to contribute to improving the quality of patient outcomes and to providing more effective patient centred care in the context of increasingly complex and ambiguous health related challenges*’ p950 (Roussi and Miller, 2014).

An appreciation of the way in which the patient arrives at a decision to proceed or not with CRMD implantation among different groups may provide a better understanding of potential disparities. This, and an awareness of their preferred informational coping style, may present the evidence required to facilitate development of a framework of tailored information and communication practices. The purpose of this would be to enable effective collaborative decision-making, to meet the demands and requirements of specific needs and situations, facilitate truly informed choices, improve the patient experience and help acceptance and adjustment to life with technology.

3.4 Theoretical Framework

The value of decision theory lies in its ability to unpack the complexity of factors, such as decision type, personal experience, goals and social context to enhance understanding of real life patient decision-making (Broadstock and Michie, 2000). It was clear from the scoping review that most studies did not have a decision-making theoretical basis. Where theory was evident, there was a variety of approaches for example, Lucas (2012) refers to the theoretical lens of humanistic nursing (Paterson and Zderad, 1976/1988). Differentiation and Consolidation (Diff Con) is a process theory concerned with the importance of alternatives in reaching a sound decision, whereby an optimal decision is derived from the consideration and differentiation of various alternatives (Svenson, 1992). Diff Con Theory (Svenson, 1992) is introduced as the theoretical basis for the evaluation of the ICD-DAS by Hazelton et al. (2014), however application to the study is neither explicit nor clearly evident. Differentiation involves attaching value to each option and then restructuring the level of attractiveness of each option until a choice can be made (Svenson, 1992). Consolidation is concerned with the post decision phase where efforts are made to reduce cognitive dissonance and avoid decisional regret (Svenson, 1992). In practice, Diff Con theory has generally been applied to non-healthcare decisions which have several alternative options (Svenson and Jakobsson, 2010). However, the binary (accept or decline) nature and seriousness of the CRMD decision option, and the fact that the post decision phase was not of immediate interest precluded the use of Diff Con theory for this study. The integrative review was based upon the Ottawa Decision Support Framework (ODSF) (Lewis et al., 2014b). The ODSF describes three steps in the decision-making process which are concerned with assessing decision support needs, provision of tailored decision support and evaluating the decisional outcomes. It has most frequently been used to guide the development and evaluation of patient decision aids. As this was not a specific aim of this study, the ODSF was not considered to be applicable here.

Carroll et al. (2011) proposed a detailed conceptual framework for further testing in practice, which attempts to contextualise the complex sequencing of the decision process, among patients contemplating acceptance or refusal of primary ICD (Figure 3.1). The model resembles several of the findings that emerged from the scoping review and was therefore considered as a conceptual basis for this study. The scoping review highlighted a number of elements that feature in the model proposed by Carroll et al. (2011). For example, the notion of passive and active approaches to decision-making, time to deliberate and influencing factors. While this model has the potential to direct research in this area, it lacks clarity and detail with respect to some aspects of decision-making. For example, ‘sense making’ does not clearly explore the interplay between individual and collective decision-making. Reference to influencing factors was limited to health state, family concerns and trust, with no consideration of other factors or reference to decision outcomes.



Reproduced With Permission. (Carroll et al., 2011)

Figure 3-1 Contextual Model Of Patient’s Decision-Making To Accept Or Decline An Implantable Cardioverter Defibrillator For Primary Prevention Of Sudden Cardiac Death

The intention of this study was to explore the sense making component in a more explicit manner and consider a broader range of potential influential factors. It was also interested in the potential relationship between coping strategies and decision-making with reference to knowledge acquisition and a decisional outcome measure. Although Carroll’s model attempts to illustrate the complexity and dynamism of decision-making, the structural arrangement of the elements was also considered to lack sufficient clarity to provide guidance and structure for this research study. Therefore, with the authors permission, Carroll’s model (Carroll et al., 2011) was used as a basis to inform the development of a conceptual map, which reflects elements emerging from the scoping review and incorporates reference to decision theory, to enhance simplicity and provide clearer direction for this study (Figure 3.2).

3.4.1 Developing A Conceptual Map

Tashakkori and Teddlie (2003) define a conceptual map as;

> '*a consistent and comprehensive theoretical framework emerging from an inductive integration of previous literature, theories and other pertinent information. A conceptual framework is usually the basis for reframing the research questions and for formulating hypotheses or making informal tentative predictions*' p704

The conceptual map was designed to represent the patient journey from clinical presentation, device recommendation and the initial response to CRMD, acceptance or refusal and decisional regret (Figure 3.2). It attempts to illustrate the potential relationships among influencing factors, the decision process and outcomes which were apparent in the literature. It was anticipated that the conceptual map intended to provide basic structure and guidance to the preliminary phase, would evolve, expand and mature as the study progressed to truly reflect CRMD decision-making. The purpose of adopting this approach was to gain a deeper understanding of the factors which influence both the process of patient decision-making, and the decision to accept and decline recommendation for primary ICD or CRT-D.

It was postulated that the response to device recommendation would stimulate a chain of events leading to a final decision. Therefore, the actual recommendation formed the starting point for this inquiry. As the general decision-making literature and the scoping review refer to individual and collective decision-making processes, the concept of whole mind : shared mind was considered to be a useful model for providing additional structure to this inquiry (Epstein, R., 2013). With respect to individual decision-making, the initial thoughts, feelings and actions in response to the recommendation were of particular interest. A key area for further investigation emerging from the scoping review was whether individual decision-making involved adoption of particular informational coping styles. Based upon the literature, it seemed that informational coping styles may predict the level of engagement with information processing. A measure of monitoring and blunting as manifest coping strategies was therefore considered appropriate for inclusion. Various assessment tools to measure monitoring and blunting exist in the literature. Chapter 4 provides a detailed analysis of the rationale for, and choice of method used to measure monitoring, and determine the extent to which it may affect decision-making.

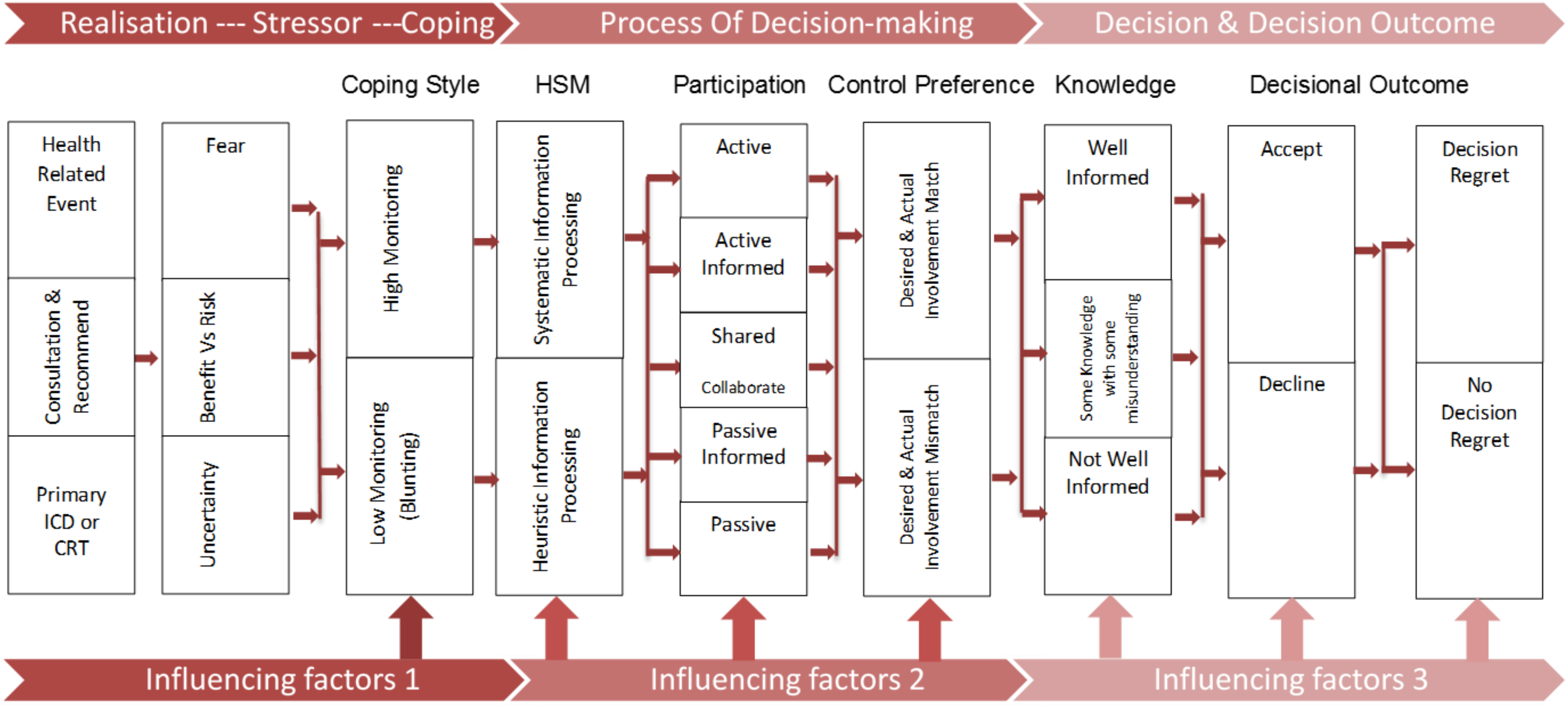


Figure 3-2 Conceptual Map Of Patient Decision-making Developed From The Scoping Review

The literature and scoping review consistently refer to the use of automatic, emotion focused and cognitive, problem based approaches to individual decision-making. In particular, the work by Kahneman (2011) on fast and slow thinking processes was of interest. Therefore, the Heuristic-Systematic Model (HSM) (Chen, S. and Chaiken, 1999) was adopted as a relevant and well used framework to guide further exploration of patient information processing. Similarly, as the work of Charles et al. (1999) on collective participation in decision-making was frequently referred to in the literature, it seemed appropriate to use their model to form the basis for investigating the level of patient participation further.

The scoping review suggested that the decision-making of CRMD patients about their treatment was not well informed. This has important consequences for informed consent and therefore the level of knowledge acquisition, recall and understanding of patients locally formed a major area of interest. As the fundamental outcome is a fully informed decision and consent, the extent to which the decision style acts as enabler or barrier to this aim was of particular interest. The degree of preference for decisional control may be one such factor and is thought to be associated with decisional satisfaction and regret. In the scoping review, Groarke et al. (2012) revealed a mismatch between desired and actual levels of participation. Yet in contrast to contemporary treatment decision-making literature, 93% of respondents in Groarke's study were satisfied with their decision to accept ICD, though it was not clear how this was established. Hickman (2010) also suggests that the Decisional Control Preferences (DCP) Scale (Degner et al., 1997b) was used in their study however they do not specifically report on the findings. Early studies using the DCP model in women with breast cancer both in Canada (Bilodeau and Degner, 1996; Hack, T. et al., 1994) and in England (Beaver et al., 1996) provided evidence that decisional preferences formed a unidimensional measure, indicating that the scale provided reliable data in this population (Degner et al., 1997b). It has since been selected in cancer treatment decision-making studies for its simplicity (Hawley et al., 2008; Caress et al., 2002), and was therefore considered appropriate for this study.

Decisional satisfaction may not be immediately established therefore a measure of initial decisional regret was considered worthwhile. Anticipated regret about decisional outcomes may affect decision behaviour, whereby relinquishing choice avoids making the 'wrong' decision and therefore avoids decisional regret (Lam et al., 2005; Edwards, A et al., 2003). This suggests a possible association between passivity and regret. The scoping review revealed that despite being in receipt of insufficient information at the time of implant there was little evidence of decision regret (Singh, N. et al., 2012; Agard et al., 2007), though explicit reference to decision styles was not made. Although there was no significant association between demographic or clinical variables and regret, Hickman (2010) found monitoring and blunting informational coping styles to be significant predictors of decision regret, when adjusted for clinical and psychological variables, suggesting the need for further exploration. Finally, the conceptual map attempts to illustrate the potential relationship among influencing factors, the decision process and outcomes. A range of socio-demographic and situational factors are frequently alluded to in the literature, however the impact upon decision-making remains inconclusive. The impact of influential factors was therefore open to further scrutiny in this study.

It is acknowledged that patient treatment decision-making is far from straightforward and may not conform to the linear model presented here. However, a linear structure was purposely designed to provide clarity and structure to the process of examination of what is in reality a complicated process. The map aims to illustrate how various decision-making processes that patients may engage with, and factors that may influence the process and the decision, might be inter-related. It also provides a beginning and end to the patient experience of interest. The purpose of developing the conceptual map was to clarify that the research question and aims posed, were appropriate and achievable. In order to ensure achievability and transparency, the three overarching aims required further division in to more manageable, measurable bite sized chunks. The conceptual map informed the development of several objectives within each aim.

Aim 1: to determine whether an association exists between socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret.

The objectives were;

i. To discover whether a relationship exists between socio-demographic characteristics and / or situational factors and self-reported coping style
ii. To explore whether demographic, situational and coping style factors influence the patients approach to decision making
iii. To determine whether demographic difference, situational context, coping style and decision approach have an effect upon acceptance and refusal of CRMD therapy
iv. To investigate whether socio-demographic characteristics, situational context, coping style, decision approach, acceptance or refusal of therapy had an impact upon decisional regret

v. To establish whether there is an association between the degree of match between desired and actual level of involvement, the final decision and decisional regret.

Aim 2: to develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed.

The objectives were;

i. To explore how patients, respond to the initial recommendation for primary prevention CRMD and determine whether it affects their engagement with decision-making
ii. To investigate the extent to which CRMD patients engage in heuristic and systematic information gathering
iii. To examine the extent of collaborative decision-making evident in current local practice
iv. To determine what factors are perceived by the patient to influence the adopted decision approach, acceptance or refusal and decisional regret.

Aim 3: to examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

The objectives were;

i. To determine whether individual characteristics, coping style, and approach to decision making influenced the level of knowledge acquisition and recall
ii. To discover whether the patient-professional interaction influenced knowledge and understanding and device acceptance or rejection
iii. To identify whether patients have enough relevant information about their cardiac condition, device indication, role function, benefits and potential complications to reach a desired decision and provide informed consent.

The conceptual map, aims and objectives then provided the basis for the choice of research methodology and the selection of the most appropriate methods required to undertake the study. Clearly identified objectives and a detailed analysis of the chosen research methods are presented in Chapters 4 and 5.

3.5 Philosophical Assumptions Underpinning The Research Approach

Critical reflection upon certain philosophical, ontological, epistemological and methodological assumptions held by the researcher was a necessary step when embarking upon this thesis because they offer an essential framework to guide the development of enquiry (Guba and Lincoln, 2005). This section presents the intellectual justification for the choice of research methodology to address the research question, followed by an overview of the specific methods adopted to achieve the study aims.

The studies identified in the scoping review had quantitative (n=6) and qualitative (n=8) designs, reflecting the diverse approaches available when addressing questions about decision-making. However, it was believed that allegiance to one of the two dominant but opposing paradigmatic positions, that of positivism / post positivism or social constructivism / interpretivism (Lincoln and Guba, 1985), would constrain discovery to an incomplete picture and was therefore inadequate in developing a more complete understanding of the process of CRMD decision-making. So, in rejecting the dogmatic either or choice of a qualitative or quantitative design, a pragmatic approach was adopted. Pragmatism is defined as;

> '*a deconstructive paradigm that debunks concepts such as 'truth' and 'reality' and focuses instead on 'what works' as the truth regarding the research questions under investigation'* p713 (Tashakkori and Teddlie, 2003).

Pragmatism does not seek to align to one particular philosophical viewpoint but rather focuses attention upon what works and solutions to problems, placing greater emphasis upon the research problem than the methods employed (Johnson and Onwuegbuzie, 2004). It embraces a pluralistic approach to explore the problem drawing upon quantitative and qualitative assumptions, allowing multiple methods and different forms of data collection and analysis in its quest to derive knowledge of the problem (Creswell, 2009). He states that;

> *'pragmatism emphasises the importance of the research questions, the value of experiences and practical consequences of action and understanding of real world phenomena'* p276 (Creswell, 2009).

A pragmatic stance was eminently suited to the breadth of inquiry required to discover answers to the research question. Alternative options such as a transformative emancipatory paradigm (Mertens, 2003) was not relevant as this study was not concerned with discrimination or oppression. Critical realism, acknowledges the existence of different types of knowledge across the ontological and epistemological spectrum and would therefore be suitable for this study (Guba and Lincoln, 2005). However, it was considered to be more concerned with theoretical rather practical knowledge generation, whereas, pragmatism presented a desirable practical and applied philosophy. Therefore, adoption of a pragmatic stance allowed the research aims and objectives to dictate the choice of methods selected from different paradigms.

3.6 Mixed Methods Research

Pragmatism is the philosophical stance most often associated with mixed methods research (Teddlie and Tashakkori, 2009; Morgan, 2007; O'Cathain et al., 2007; Johnson and Onwuegbuzie, 2004). Mixed methods research (MMR) has been described as the third paradigm or methodology based upon ontological and epistemological pluralism (Morgan, 2007). MMR is construed as the integration of quantitative and qualitative approaches throughout or at points during the study (Teddlie and Tashakkori, 2009). It was selected for its ability to address exploratory and confirmatory research questions and allow the use of different methods to address different aspects of the same research question and so broaden understanding, comprehensiveness and corroboration of the research problem (Klassen et al., 2012; Johnson et al., 2007; O'Cathain et al., 2007; Bryman, 2006; Greene et al., 1989). As such, it offers the opportunity to exploit the complementary strengths of quantitative and qualitative methods. That is, the breadth and depth of inquiry respectively, to explore and characterise the complexities of decision-making by different groups more fully than either approach in isolation (Curry et al., 2013; O'Cathain et al., 2007; Creswell and Plano-Clark, 2007; Bryman, 2006). Furthermore, MMR ‘complementarity’ permits findings to supplement and confirm one another and so enhance validity, trustworthiness and provide stronger inferences than a single approach in isolation. It can also offset the disadvantages associated with certain methods when used alone (Ostlund et al., 2011; Teddlie and Tashakkori, 2009; Greene and Caracelli, 1997).

MMR is not without controversy and challenge (Creswell, 2011; Teddlie and Tashakkori, 2003). There are continued and confusing disagreements over definitions (Creswell, 2011; Johnson et al., 2007) and preferred terminology ranging through ‘mixed approaches’ (Johnson and Christensen, 2012), ‘mixed research’ (Johnson et al., 2007) or ‘mixed methodology’ (Teddlie and Tashakkori, 2009). So what is mixed methods that multi-method is not? ‘Multi-method’ research, or ‘triangulation’ remains affiliated to one research paradigm but may collect and analyse data from alternative approaches in isolation (Denzin, 2012; Teddlie and Tashakkori, 2003). The ‘complementary strengths thesis’ supported the separate inclusion of both approaches as independent strands within one study designed to address the research problem (Morse, 2003). Such an ‘embedded design’ prioritises one principle methodology (quantitative or qualitative) but allows for the inclusion of supportive data from the other method (Greene et al., 1989). However, the issue of dominance of one approach, usually quantitative over the other was considered to be problematic, and a combination of approaches firmly committed to an ethos of equal standing was preferred. Furthermore, undertaking each strand in isolation was believed to be inefficient in terms of failing to embrace opportunities to meaningfully compare, contrast and cross validate findings from each type of data in a confirmatory or contradictory way (Creswell, 2003).

In addition, there has been a resurgence of interest in the meta-theoretical paradigm debate revolving around the irresolvable questions regarding the incommensurate, incompatible philosophical differences between quantitative and qualitative approaches, said to invalidate their combination and previously referred to as the ‘incompatibility thesis’ (Kuhn, 1996; Lincoln and Guba, 1985). The conviction of notable critics that “*paradigm, epistemological and methodological difference between and within QUAN/QUAL frameworks”* p83 matter, is acknowledged (Denzin, 2012). That is, the debate regarding the significance, compatibility and relative value of the two dominant but opposing paradigmatic positions and the relevance of epistemological and methodological distinctions between them was recognised (Morgan, 2007). However, it was considered to be a matter of academic discourse rather than of practical value, therefore further discussion was beyond the scope of this PhD chapter.

Notwithstanding the ongoing feud over the pervasive post positivist bias which appears to favour quantitative dominance over qualitative, and led critics to describe MMR as ‘superficial bilingualism’ with questionable added value (Creswell, 2011), MMR was considered appropriate for this study. MMR appreciates the equal value of quantitative and qualitative worldviews to develop a deep understanding of the phenomenon. It is not merely a framework for the collection of qualitative and quantitative data but promotes the meaningful overlap and integration of both data sets during data collection, analysis, integration and inference techniques (Creswell and Plano-Clark, 2011; Tashakkori and Teddlie, 2008). The successful integration of both approaches, leading to the ‘compatibility thesis’ is said to have largely discredited the discordant position (Teddlie and Tashakkori, 2009; Howe, 1988). The ‘compatibility thesis’ focused upon the complementarity of quantitative and qualitative approaches, accepted inter-subjectivity (juxtaposition of a single reality and unique individual interpretations) and embraced a ‘what works’ pragmatic perspective as its philosophical basis (Teddlie and Tashakkori, 2009; Bryman, 2007; Morgan, 2007; Howe, 1988). Thus, MMR embraces an ‘interactive continuum’ rather than a dichotomy between quantitative and qualitative methodologies (Newman et al., 2003). Furthermore, this research endorses the opinion that allegiance to the purist view that quantitative and qualitative approaches cannot be merged, threatens opportunities for the advancement of science (Onwuegbuzie and Leech, 2005). Thus, for this study the importance of using the most appropriate method to answer the research problem, outweighed further consideration of alleged paradigmatic incommensurability. In fact, as MMR is still relatively new, further studies can only serve to confirm or refute the true possibility and benefits of data mixing and integration and thus add to the debate. MMR presents;

> “*the opportunity to transform* (paradigmatic) *tensions into new knowledge through a dialectical discovery*” p4 (Creswell, 2011).

Additionally, any targeted support measures arising from the findings of this study, would not only be based upon valid and reliable statistical data but they would represent the voice of the patient, giving weight to the utility of the outcomes (Bryman, 2006). On the other hand, ‘divergence’, when qualitative and quantitative findings from each strand reveal different or even contradictory findings, may be equally valuable in verifying the need to re-evaluate the conceptual map (Ostlund et al., 2011; Teddlie and Tashakkori, 2009). Lastly, MMR relies upon researcher expertise in quantitative and qualitative methods and substantial time commitment (Creswell and Plano-Clark, 2011). As researcher training is fundamental to PhD study, developing greater insight into the strengths, weaknesses and skill in the use of alternative approaches is essential, and part time study goes some way to facilitate the time investment. In conclusion, this study embraces ‘*the 1 + 1 = 3 integration challenge*’ p116 posed by (Fetters and Freshwater, 2015).

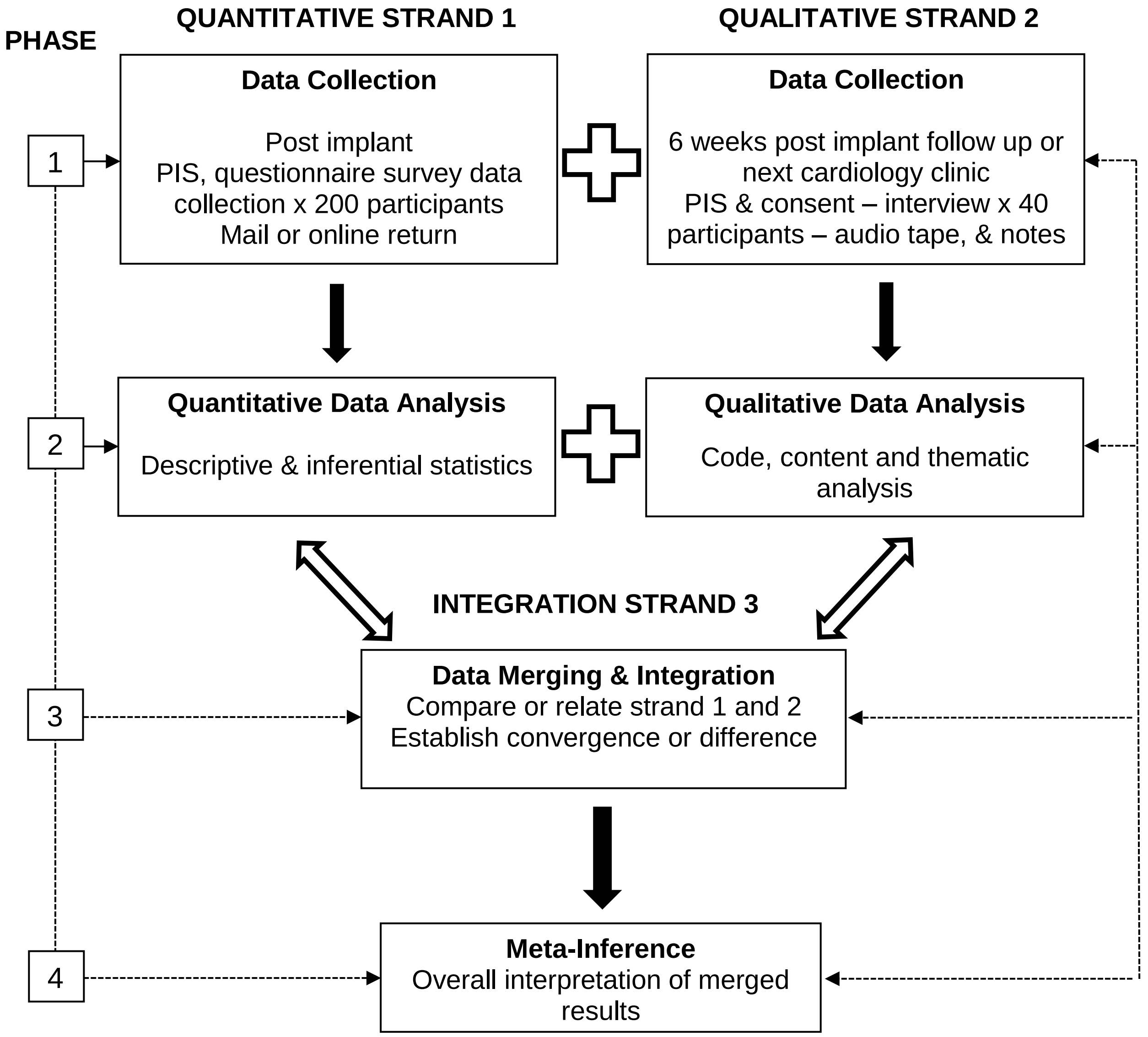
3.7 Typologies Of Mixed Methods

Ad hoc methods mixing could threaten validity (Denzin, 2012; Morse and Niehaus, 2009), therefore the complex and distinctive nature of MMR required careful planning of the timing, weighting and method of data mixing (Creswell and Plano-Clark, 2011; Creswell, 2009; Teddlie and Tashakkori, 2009; Creswell, 2003). Mixing (integration) can occur at the study design, the methods and / or the analysis and interpretation stages.

3.7.1 Mixing At The Design Stage

Mixed methods designs may be emergent, whereby one method is found to be inadequate in addressing the research problem and therefore supplemented by the addition of a second approach (Morse and Niehaus, 2009). Teddlie and Tashakkori (2009) describe five, dual strand mixed methods designs. Sequential mixed designs involve two, interactive chronological phases, whereby questions from one strand emerge from or depend upon the other strand, therefore research questions are related to each other and may evolve as the study progresses (Teddlie and Tashakkori, 2009). Explanatory sequential models prioritise quantitative data collection and analysis to answer the research question with secondary qualitative analysis to explain the quantitative findings. Exploratory sequential methods prioritise the qualitative phase and allow a secondary quantitative phase to test or generalise the findings (Teddlie and Tashakkori, 2009). As such, the issue of dominance of one phase over the other, resembles ‘embedded designs’ and was considered to be philosophically problematic. The rationale for selecting a mixed approach was to address different aspects of the phenomena of interest. Therefore, in collaboration with SUC’s, the data collection schedules were independently designed, to collect data from alternate perspectives, prior to commencing the study. This arrangement precluded the sequential design. In addition, by their very nature, sequential projects are longitudinal and as such require a relatable timeframe. A sequential design was considered to be impractical due to time constraints on data collection within a PhD study. Alternative options included multi-level parallel or sequential designs, meaning that the addition of more strands increases the number of possible permutations. These allow mixing to occur at multiple levels of analysis and fully integrated mixed designs require mixing to occur in an interactive manner at all stages. These options are by design more complicated than the others and therefore considered beyond the scope of the novice researcher.

A multi-phase, multi-strand, parallel concurrent, convergent mixed design, considered to be the traditional, most familiar and simplest MMR model, was selected as the most appropriate to achieve the research aims. Phase 1 involves the use of different data collection methods in discrete strands of the research. Teddlie and Tashakkori (2009) described this as ‘between strategies’ MMR data collection. In order to generate sufficient Strand 1 data for statistical analysis, it was anticipated that all participants would complete the survey. The selection of a smaller sample for Strand 2 interviews was therefore drawn from survey completion. That is, all Strand 2 participants would be included in Strand 1. However, the interview schedule was specifically developed to address aim 2, and was therefore not derived from the survey answers. As such, this study was described as a parallel rather than sequential design. At phase 2, the different data sets are analysed independently. This method was favoured as it gives equal priority to the independent but simultaneous data collection (phase 1) and analysis (phase 2) of separate quantitative and qualitative strands, within a similar time frame. Convergence occurs at phase 3 when the two strand data sets are ‘mixed’ or integrated to establish any congruence or distinction in the findings (Creswell and Plano-Clark, 2011; Creswell, 2009). This formed Strand 3. Phase 4 focuses upon interpretation of the findings. Figure 3.3 depicts the correlation between the four phases and the 3 strands.



Key:

✚ denotes concurrence

⟺ denotes data mixing (Creswell, 2014; Creswell and Plano-Clark, 2011; Morse, 2003)

Figure 3-3 The Concurrent, Parallel, Convergent Mixed Methods Design

3.7.2 Mixing At The Methods Stage

Four approaches to data integration at the methods level have been described in the literature (Fetters et al., 2013). ‘Connecting’ is linking the data by sampling. This was not considered necessary for this study. ‘Building’ is where data from one strand informs the data collection method of another. This requires a sequential design and was therefore not planned for this study. However, as survey completion was planned to precede the interview, it was possible that the survey may inform the interview discussion. ‘Embedding’ involves links between data collection and analysis at multiple points (Fetters et al., 2013). Alternatively, the fourth option does not involve mixing at the sampling or data collection stages. This was the favoured position for this study. Creswell and Plano-Clark (2011) describe the process of integration within concurrent, convergent MMR as ‘merging’. ‘Merging’ is where parallel data collection and separate analysis of the data sets (Strands 1 and 2) occurs prior to combination for further analysis (Strand 3). This variation of convergent MMR methods was chosen because its technical simplicity in comparison to other versions makes it the most commonly used approach in practice (Fetters et al., 2013).

3.7.3 Parallel Data Collection And Analysis

Variation in the focus of each research aim commanded the collection and analysis of both quantitative and qualitative data. Quantitative data methods were considered to be the most appropriate for aim 1, whereas qualitative methods were the preferred option for aim 2. Aim 3 was interested in asking what, how and why questions and therefore presented the opportunity to use both methods to gather different but pertinent types of information. Phase 1 refers to the independent but simultaneous data collection of separate quantitative and qualitative strands, within a similar time frame. In phase 2, the quantitative and qualitative strands were analysed separately. It seemed appropriate to consider the methodological merits of each strand adopted within this MM study.

3.7.3.1 The Quantitative Strand 1

The first and third research aims were exploratory in nature. The first aim sought to confirm or refute the existence of an association between, and the potential predictive nature of a range of factors, which may influence the patients’ decision approach, the decision to accept or decline therapy and decisional regret to inform more targeted support mechanisms. The third aim was concerned with the patient-professional interaction and modes of information gathering. The confirmatory, theory driven nature of quantitative research, whereby a-priori deduction of research questions from a conceptual framework are tested using numerical data collection and statistical analyses, are often employed (Teddlie and Tashakkori, 2009). Certain pre-defined elements arising from the literature and featured in the conceptual map, such as monitoring, source of information gathering and decisional control preferences, formed the basis for investigation. As such, it lends itself to the collection of self-reported, numerical data for quantitative analysis once the entire sample had been gathered. This was considered to be the most appropriate, effective and efficient means of gathering this type of information.

A number of quantitative research designs are at the disposal of any researcher. Although considered to be less powerful than randomised controlled trials (RCT's) and quasi experimental research, a non-interventional design, which seeks to observe, count and measure characteristics of the phenomena of interest, and study variables as they exist was considered to be more appropriate for this study (Gray, J. et al., 2017). This could be cross sectional survey which collects data over a pre-specified period of time to provide a 'snap shot' of the phenomena, or a retrospective case control study, involving retrospective comparison of groups for possible causal attributes. The latter method is reliant upon the availability and accuracy of previously collected data. As this study focuses upon a specific group of individuals recommended for CRMD, a prospective, comparative, correlational cohort study, utilising a survey method of data collection was considered to be the most appropriate for predicting population attributes and behaviours, and assessing patterns and strength of association between variables (Gray, J. et al., 2017; Gerrish and Lacey, 2010).

This approach typically distances the researcher from the researched to prevent influencing the results, in the quest to establish facts or truths about reality. Its strengths lie in the prospect of accurate measurement, ability to measure comparison, examine the strength of association between variables of interest and hypothesis testing (Castro et al., 2010). As such, survey methods are concerned with collecting data which is independent of human beliefs or behaviours and is considered to be context and value free. Therefore, a limitation of survey methods is the fact that they detach information gathered from the 'real world' context. Structured methods of data collection would therefore provide limited depth, detailed explanation or understanding of patients real life experience of decision-making. Chapter 4 presents a detailed analysis of the quantitative methods employed in Strand 1.

3.7.3.2 The Qualitative Strand 2

In contrast to the positivist stance, social constructivism is interested in a fully contextualised view of the ‘whole person’, and embraces a subjective epistemology and qualitative methodology, which relies upon interaction between the researcher and the researched in order to make sense of the lived experience of the phenomenon (Berger and Luckmann, 1991; Lincoln and Guba, 1985). Despite significant opposition in the late 20th century, by critics of qualitative methodology, qualitative research methods are now widely used and accepted within healthcare science. On this basis, a qualitative methodology was well disposed to explore and explain how and why adults, who have been recommended for CRMD, approach and reach their decision to accept or decline implantation. This therefore formed the basis of strand 2, which was designed to address the second and third research aims. The second aim was concerned with the subjective, experiential experience of decision-making from the patient’s perspective. The third aim hoped to assess the level of knowledge acquisition and recall. As such, a deeper understanding of the complex, uncertain and unpredictable nature of CRMD decision-making from the patient perspective could be revealed.

Several alternative strategies of qualitative inquiry exist. They are broadly classified as interpretive (phenomenology, grounded theory, ethnography, case study) or critical (action research, feminist research), and each is defined by a particular focus (Denzin and Lincoln, 2011; Holloway and Wheeler, 2010). Elements of each approach (except ethnography) could be applied, though phenomenology most closely described the focus of this study. Phenomenology is interested in the collective lived experience of a particular phenomenon, described by a group of individuals (Creswell, 2013). However, it seeks to eliminate any influence resulting from the experience of the researcher upon data collection or analysis. Therefore, the notion of researcher ‘bracketing’ prior knowledge or experience so as not to influence interpretation was rejected in favour of a more reflexive approach. Grounded theory is concerned with inductive theory generation when little prior knowledge and understanding of a phenomenon exists (Corbin and Strauss, 2015). The existence of several available decision theories as a basis for this inquiry mitigated against a grounded theory approach. As ethnography requires the researcher to study group culture and beliefs from within, it was not appropriate for this study (LeCompte and Schensul, 2010). Case study focuses upon an in-depth exploration of a particular process, activity, event or individual(s) (Yin, 2014). Though widely used by several disciplines, particularly social science, variation in the definition, application and validity of case study research has been criticised as confusing and therefore not pursued further (Harrison et al., 2017; Crowe, S. et al., 2011; Anthony and Jack, 2009). Narrative research relies upon participants written accounts of their stories and was therefore not appropriate for this study (Clandinin, 2000). Critical approaches that emphasise change, or emancipation, as part of the research process, with participants playing a key role in all aspects of the design and implementation of the study were also not applicable.

Qualitative description represents an alternative, generic approach to qualitative inquiry (Sandelowski, 2010; Sandelowski, 2000b). Using a generic approach, the qualitative component within this thesis was defined as;

> '*that which is not guided by an explicit or established set of philosophic assumptions in the form of one of the known qualitative methodologies*' p2 (Caelli et al., 2003) but which seeks to '*discover and understand a phenomenon, a process or the perspectives and world views of the people involved*' p11 (Merriam, 1998).

This generic approach was employed as it fits with a pragmatic stance allowing selection of the most appropriate methods to achieve the research aim. Sandelowski (2000b) described qualitative description as an unacknowledged rather than new distinctive categorical method, which may draw upon techniques associated with other qualitative strategies. Compared with traditional qualitative approaches, a descriptive strategy is considered to be the least theoretical, though not a-theoretical and therefore the lowest ranked on the qualitative hierarchical scale (Sandelowski, 2010). Therefore, to enhance its standing a generic position requires clarity of and congruence between methodology and methods, such that they can be distinguished from other designs. This requires strategies to ensure rigour and an analytic lens through which the researcher examines the data (Cooper and Endacott, 2007). This was addressed through the clear identification of methods for each strand and the application of Framework Analysis to facilitate examination of the data (Ritchie et al., 2014). It also relied upon procedures for ensuring validity and reliability, accepted as appropriate concepts for achieving rigour (as opposed to terms such as credibility and dependability) and reflexivity (Caelli et al., 2003; Morse et al., 2002; Mays and Pope, 2000). That is, the close interaction between researcher and researched in order to explore the meaning individuals attribute to their experience. It requires the researcher to critically reflect upon their potential influence upon knowledge generation throughout each stage of the study in a clear and transparent manner.

Semi-structured methods such as open ended interviews are preferred in order to explore the subjective experience of decision-making in a more detailed and complementary manner (Creswell and Plano-Clark, 2011; Creswell, 2009; Teddlie and Tashakkori, 2009). However, by its very nature, large volumes of narrative data collection limit the number of participants and therefore the external validity of the findings. Framework analysis was considered to be the most appropriate method of data analysis, which commenced alongside data collection. Chapter 5 presents a detailed analysis of the qualitative methods employed in Strand 2.

3.7.4 Mixing At The Analysis And Interpretation Stage

A common MMR approach involves data mixing and merging at the analysis and interpretation stage (Fetters et al., 2013). Merging in convergent approaches is said to;

> '*surpass the mere summation of qualitative and quantitative evidence. It is in the dynamic merging of the two forms of data that they become greater than the sum of their parts'* p156 (Plano-Clark et al., 2010).

Phase 3 of this MMR was to merge the independently analysed data sets. The appeal of mixing the data at this stage, rather than before was that it avoided the practical complexity of attempting to mix at the sampling and data collection stage. It also allowed the merits and nuance of the separate data sets to be fully recognised. Following independent analysis, analysis of the mixed data ensued.

3.7.4.1 The Integrative Strand 3

Strand 3 was planned so that both strand 1 and 2 data sets could be merged and integrated to facilitate true mixing of the data at the interpretation stage (Fetters et al., 2013; Teddlie and Tashakkori, 2009). Data integration was important in determining the level of congruence between strand 1 and 2 datasets, by examining concordance, consistency or discrepancy within the results. Using the data sets to enrich or explain each other can enhance, challenge or quantify the findings from either component and so strengthen the quality and validity of the findings (Creswell, 2015; Curry et al., 2013; Creswell and Plano-Clark, 2011; O'Cathain et al., 2007a). This method suited the acquiring of different but complementary data to answer related aspects of the same research questions (Creswell and Plano-Clark, 2011) and so develop a more complete picture of CRMD decision-making. It was hoped that merging the data may facilitate cross validation and therefore add more weight to the inferences made (Fetters et al., 2013). Data merging and analysis is discussed in detail in Chapter 6.

3.7.4.2 Meta-Inference Of Findings

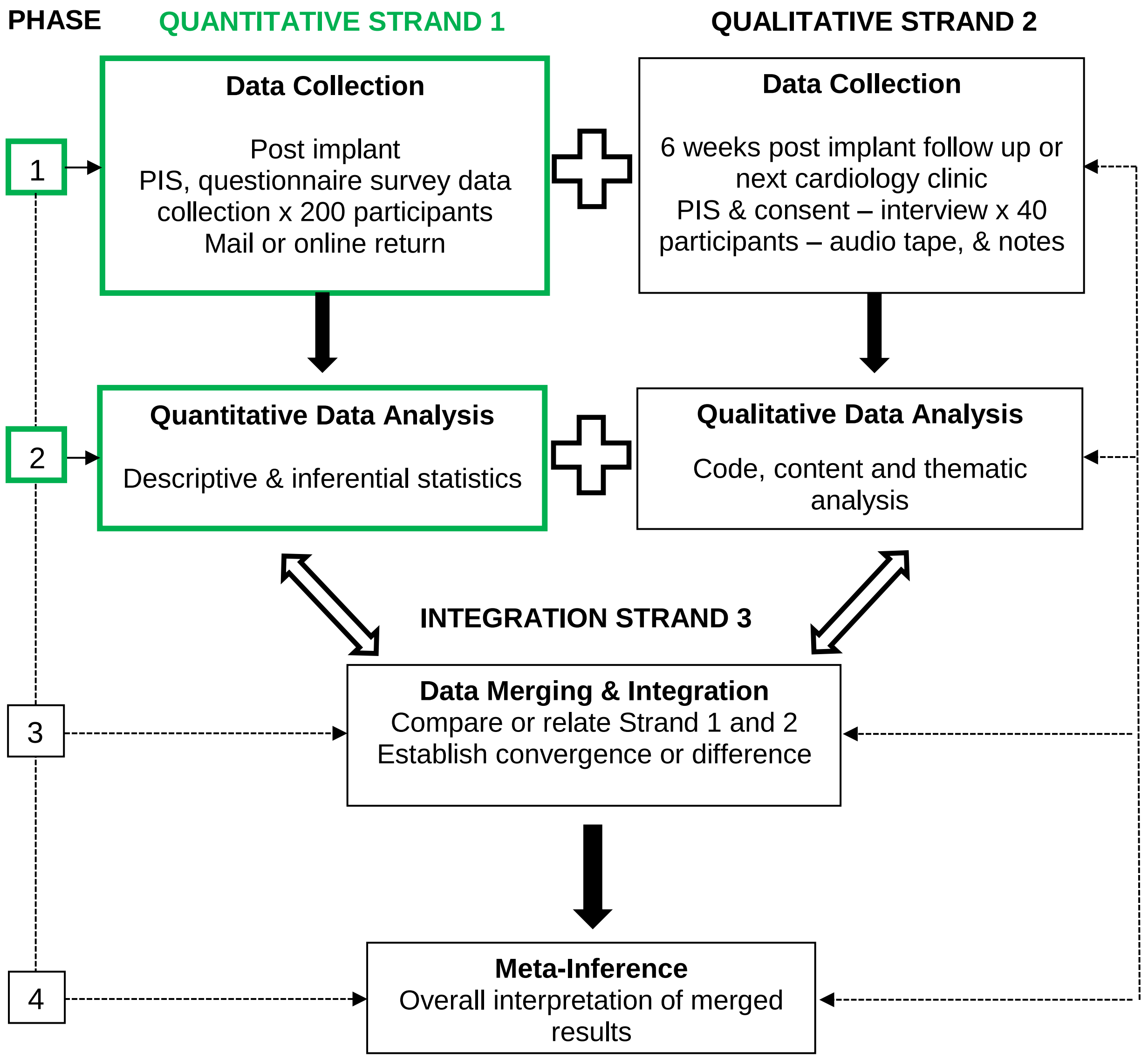
Phase 4 meta-inference was the process of consideration and interpretation of inferences derived from all data types and the combined analyses. It can provide confirmatory (bridging) and contradictory (bracketing) evidence leading to new understanding of the phenomena (Klassen et al., 2012; Onwuegbuzie and Teddlie, 2003). This formed the basis for the discussion chapter 7. The methodology and methods outlined here were considered to be the most time efficient method for a PhD thesis and according to Creswell (2009) can result in well validated and substantiated findings.

Chapter 4 is concerned with the quantitative Strand 1 of this MM inquiry. It will provide the rationale and a detailed analysis of the research methods selected to undertake step 1 of Strand 1. In step 2, the process of statistical analysis will be described in detail and the findings will be presented in table and narrative format.

Chapter 4
Strand 1 Methods And Findings

4.1 Introduction

Chapter 4 is concerned with phases 1 and 2 of this empirical mixed methods (MM) study (Figure 4.1). It presents the methods and findings of the quantitative Strand 1.



Key:
✚ denotes concurrence

⇔ denotes data mixing (Creswell, 2014; Creswell and Plano-Clark, 2011; Morse, 2003)

Figure 4-1 Concurrent Parallel, Convergent Mixed Methods Design – Strand 1

The conceptual map (Chapter 3), based upon the findings of the scoping review was designed to provide structure and guidance to inform the requisite study design and methods to answer the research question. Strand 1 adopts a quantitative approach to investigate aims 1 and 3. The research aims were populated with a number of objectives to provide clarity and structure for this phase of the project.

Aim 1: to determine whether an association exists between socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret.

The objectives were;

i. To discover whether a relationship exists between socio-demographic characteristics and / or situational factors and self-reported coping style
ii. To explore whether demographic, situational and coping style factors influence the patients approach to decision making
iii. To determine whether socio-demographic difference, situational context, coping style and decision approach have an effect upon acceptance and refusal of CRMD therapy
iv. To investigate whether socio-demographic characteristics, situational context, coping style, decision approach, acceptance or refusal of therapy had an impact upon decisional regret
v. To establish whether there is an association between the degree of match between desired and actual level of involvement, the final decision and decisional regret.

Aim 3: to examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

The objective was;

i. To determine whether individual characteristics, coping style, and approach to decision making influenced the level of knowledge acquisition and recall.

4.2 Strand 1 Methods

4.2.1 The Sample

All patients planned for first time primary CRMD implantation and all decliners across four regional implant centres were eligible to participate. Unlike ICD device therapy alone, biventricular CRT devices may represent an improvement in heart failure symptoms for some, and as such, offers an additional incentive to choose device therapy which may influence decision making. CRT may offer pacing function only (CRT-P) or may include a defibrillator component (CRT-D). Studies to date have not focused specifically upon the initial thoughts of patients with heart failure faced with a recommendation for CRT. Recipients of CRT-P devices were therefore included as a comparator to determine the extent to which defibrillator function affected decision making. Patient’s requiring a device upgrade, system change, removal or secondary indication were excluded.

Inclusion criteria:

1. Recommended for first time primary prevention CRMD, regardless of indication and device type
2. Adults (>16years) without severe neurological impairment (to enable informed consent)
3. Sufficient command of English to complete a questionnaire and capacity to provide informed consent.

A predicted sample size was calculated with the assistance of a statistician. Several methods exist to determine how many cases are required to power multivariate regression analysis, to explore the adjusted effect of potential predictors upon the four primary outcomes. They were adopted coping style, decision approach, acceptance or refusal and decisional regret. Peduzzi et al. (1996) recommend a sample based upon ten cases per variable. The highest number of variables (n=14) is associated with the fourth primary outcome of decisional regret, therefore recruitment of up to 140 participants was recommended for this study.

Although probability techniques would ensure that all candidates have a calculable chance of being represented in the data, it is unclear whether they can be truly random or whether failure to recruit, participant non response and attrition in fact lead to a ‘self-selected’ convenience sample (Teddlie and Tashakkori, 2009). Therefore, a convenience sample of patients presenting to each site was employed. Self-selecting participation by return of questionnaire and presentation for interview may lead to sampling bias and findings may not represent the whole population of potential ICD recipients (Silverman, 2005). However, it was hoped that 140 respondents would be sufficient to enhance external validity. Although the inclusion criteria was broad, women, black and minority ethnic groups and those who declined a device were likely to be smaller in number, therefore more difficult to reach. However, stratification was unlikely to overcome this as the study was reliant upon the patients presenting to clinic during the data collection period. So, the desire to capture participants from all groups was emphasised with the first point of contact care providers.

4.2.2 Study Setting And Access

Adult patients (>16years) recommended for primary CRMD were recruited from four implant centres in Yorkshire, labelled C, L, S and W. A preparatory discussion with relevant consultants, specialist cardiac nurses and physiologists to gain trust and understanding of the nature of the study and eliminate any concerns of the gate keepers occurred between January and March 2016. Permission for preliminary observation of the patient experience at the consultation phase with various healthcare professionals was agreed, to establish background information and insight into the organisation, and content of service delivery at each site once ethical approval had been granted. Field notes were collected to help make sense of the chronology of events experienced by the participants, and determine the level of detail of information giving[3]. This provided a reference point for comparison with the patients information recall during data analysis. Formal data collection was not planned for this preparatory stage.

Recruitment posters were posted with permission in clinical areas at each implant site. A key member(s) of the direct care teams, such as the specialist nurse, physiologist or pre-assessment nurse, approached prospective participants at implant or pre-assessment with a form, requesting permission for the primary investigator (PI) to make contact with the patient post implant, via a preferred time and method[4i]. Decliners received a similar form from the consultant or cardiac ICD specialist nurse following the consultation at which they opted to decline the device[4ii]. To avoid introducing additional influence into the decision-making process, recipients were not formally approached by the PI until the device had been implanted. Implant dates were verified via the pre-assessment nurse or admissions secretary to ensure that this occurred. Those who declined were approached when prompted to do so by the consultant or specialist ICD nurse.

3 Field Notes For Clinic Observation, 4i and 4ii Permission To Contact Request Forms are available in the supplementary information.

Seventy three patients were approached between January 2017 and May 2018. This was a much slower and less fruitful process than had been anticipated given the number of implants currently undertaken. Despite having R&D approval, apparent site related reasons for this poor recruitment included unplanned sick leave, staff movement to other areas or general business of key direct contact team members, and conflict with another trial. Several strategies were employed in an effort to improve access including distribution of posters in pacemaker and outpatient clinics, several face to face, email and telephone prompts to clinicians and contact with research teams with variable effect. Finally, HRA and R&D approval was sought and eventually agreed in February 2018 to approach a fifth participant identification centre (PIC) site, labelled R. Despite local enthusiasm, data collection between February and July 2018 failed to elicit any further participants. Permission to contact forms were collected periodically from each site. The PI contacted potential participants via the agreed mode and time to explain the purpose of the two strand study, and gain permission to email / post a Strand 1 study pack which included a cover letter[4iii], patient information sheet (PIS)[4iv] and pre-paid postal return of an enclosed questionnaire (Appendix I). Instructions on how to access online completion were included and consent to participate was implied on questionnaire return. At this time, permission was sought from the participants to send one reminder at 4 weeks post initial contact to prompt a return of the questionnaire.

4.2.3 The Questionnaire Design And Administration

A self-reporting, structured questionnaire was selected as an inexpensive, quick and easy method of generating a considerable volume of data, on a wide range of characteristics and factors which may affect decision making. It was relatively short, taking approximately 15-20 minutes to complete, and self-explanatory to enhance accuracy and reduce the risk of attracting missing data. Reliance upon postal response often succumbs to low return rates and attrition may be as high as 70% threatening external validity (McKenna et al., 2010). Measures employed to optimise response rates included, personal contact with patients, a simple questionnaire design and good accompanying cover letter with instructions for completion[4iii], a stamped addressed envelope for return, assurances of anonymity and confidentiality, and follow up of non-responders at four weeks (Gerrish and Lacey, 2010). Lastly, instructions on how to access an online version using the Bristol Online Survey (BOS) service was included. The questionnaire was developed and tested with the involvement of a service user group. A specialist ICD nurse approached three device recipients who were willing to be involved. An initial meeting with the PI provided a sense of their experience and the

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4iii Cover Letter and 4iv PIS are available in the supplementary information.

factors they considered to be most important for decision-making. Issues related to who, when, how much, time taken and what information they received were particularly notable. This provided the foundation for the development of a survey comprising six sections. The conceptual map generated from the scoping review also provided structure and guidance for content inclusion.

4.2.3.1 Socio-demographic And Situational Information

Section 1 and 2 were designed to collect socio-demographic data to allow comparison among groups. This included gender, age, religion, ethnicity, marital status and an indicator of social support (Q1 to 6).

One particular area of interest highlighted within the scoping review, was the association between health literacy, information gathering, decision approach and level of engagement (Vosbergen et al., 2013; World Health Organisation, WHO., 2013; Matlock et al., 2010). Health literacy (HL) is defined as;

> *‘the degree to which an individual can access, process and comprehend basic health information and services in order to inform and participate in health decisions’* p48 (Magnani et al., 2018).

An association between symptom burden, diminished cognitive function, low health literacy, depression and passivity (Allen et al., 2008; Bekelman et al., 2007; Dickson et al., 2007; Rutledge et al., 2006) has been advanced to explain poor knowledge acquisition and understanding (Polacek et al., 2007; Fagerlin et al., 2006; de Haes, 2006). Paasche-Orlow and Wolf (2007) developed a conceptual model which illustrates the link between HL, an individual’s ability to access and use healthcare and health outcomes. It also identifies the socio-demographic characteristics as well as cognitive and physical abilities which affect HL. In the scoping review, Matlock et al. (2010) described a highly complex set of influencing factors often present and which may be magnified among heart failure patients contemplating CRMD, such as diminished cognitive function, low HL and depression which may influence a more passive approach. Low levels of HL have been associated with limited participation in health screening, poor understanding of conditions and treatment plans, poorer health outcomes and increased mortality (Rowlands et al., 2013). Levels of HL were therefore worthy of consideration. An awareness of HL may predict and then guide the selection of appropriate information materials.

On this basis a number of HL assessment tools were considered, including the Newest Vital Sign (NVS-UK) (Rowlands et al., 2013), HealthLiTT (Hahn et al., 2011), REALM (Ibrahim et al., 2008) and TOFHLA (Parker, R. et al., 1995) amongst others. However, they are either country or disease specific (cancer, diabetes, nutrition), individual or population based, limited to recognition of medical terminology or tend to focus upon reading ability or print literacy (Clancy, 2009; Pleasant, 2009). While numeracy, literature, language and communication skills are often considered, the ability of individuals to access, appraise and apply health relevant information, and the impact of memory recall, assertiveness and confidence of the individual and significant others is frequently omitted. Thus, despite the prevalence of measures of HL, a systematic review concluded that current instruments continue to rely heavily upon functional literacy measurement and generally lack consistency and reliability (Altin et al., 2014; Rowlands et al., 2013). Furthermore, they tend to be lengthy, complicated and some rely upon a degree of access to, and computer literacy. Even the shortest scales, such as the Short Assessment of Health Literacy (SAHL) with 18 items was too long to add to a 6 section survey. In addition, the NVS-UK (Rowlands et al., 2013) related to calorific values in food did not seem to be pertinent to CRMD decision-making.

Yet, as information gathering and knowledge recall were central to this thesis, reference to HL was considered to be important. It is acknowledged that HL is not simply related to a lack of skills but rather a multifactorial lack of opportunity to develop them. Therefore, without the inclusion of a valid assessment tool, reference to a proxy estimate of aptitude for HL using survey data gathered was incorporated. Educational status and social determinants of health such as ethnicity and socio-economic status have been associated with HL (Rowlands et al., 2013). Smith, S. et al. (2009) report a direct link between a lower level of education, lower HL literacy, and vice versa. Subsequently, Yost et al. (2013) also found a significant association between cognitive ability, education and HL after adjusting for variables such as age, ethnicity and condition. Therefore, although information pertaining to the level of educational attainment and occupational status (Q 7 to 9) are just two of many factors likely to affect HL, the combination of domains and concepts to provide a crude estimate of a lower or higher index of HL, was considered appropriate for this study.

Participants were assigned a value of between 1 and 3 points for the level of formal education received and between 1 and 5 points for their occupational status (Table 4.1).

Table 4-1 Crude Estimation Of Aptitude For Health Literacy

Years In Formal Education	**Points**
< 11 years i.e. Up to CSE, ‘O’ Level, GCSE	1
11 to 13 years i.e. ‘A’ Level, Certificate, Diploma	2
>13 years i.e. Bachelors / Master’s Degree, PhD	3
Occupational Status	**Points**
Unskilled Manual	1
Semi-skilled Manual	2
Skilled Manual / Clerical	3
Managerial	4
Professional	5
Estimated Aptitude For Health Literacy (HL)	**Composite Score**
Lower Aptitude	2 to 5
Higher Aptitude	6 to 8

Participants were then divided in to two categories based upon the composite score which could range from 2 to 8. A judgement was made to assign those with a composite score between 2 and 5 to the lower aptitude category and 6 to 8 to the higher aptitude category. This was based upon the fact that a score of $\leq$5 could only be attained from either a lower educational level and/or lower occupational status. Whereas, a score $\geq$6 could only be attained if the participant had a higher educational and/or occupational level. In order to verify application of the scoring tool to the data, PM and JM selected 5 (10%) random cases each and applied their estimates of lower or higher aptitude. 100% agreement was reached adding credence to the process of estimation.

Section 3 (Q10 to 13) and 4 (Q14 to 16) covered study specific situational questions related to cardiac condition, symptom severity, indication and device type, and details of the recommendation. The questions (17 to 21) pertaining to information exchange and knowledge recall were developed specifically from insight gathered from the service users. Excepting, Hazelton et al. (2014) and Hickman et al. (2010 and 2012) the scoping review studies relied solely upon researcher developed questionnaires with unconfirmed validity and reliability. As sections 1 to 4 of this questionnaire depended upon a set of researcher based questions, a degree of researcher influence is acknowledged. However, this study also included pre-validated instruments in sections

5 and 6, designed to measure three key constructs that had emerged from the literature. They were informational coping strategies, decisional control preference and decisional regret. This allowed collection of numerical data for statistical inference and modelling to determine whether associations existed which would allow predictive insight.

4.2.3.2 Informational Coping Styles

Section 5 (Q22 to 25) was concerned with participant informational coping styles. In the face of potentially life threatening information, individuals may use two cognitive coping styles (Miller, 1987). Monitoring, refers to seeking threat relevant information and blunting is a tendency to avoid such information and engage in distraction techniques. Several measures of informational coping based upon the theoretical models of Miller and Krohne exist. They are the Threatening Medical Situations Inventory (TMSI) (van Zuuren et al., 1996; van Zuuren and Hanewald, 1993), the Mainz Coping Inventory : Vigilance and Cognitive Avoidance (Krohne, 1993), the Miller Behavioural Style Scale : Monitoring Blunting (MBSS) (Miller, 1987) and the Coping Orientation To Problems Experienced (COPE) Scale (Carver et al., 1989).

Although the psychometric quality of coping measures is important, de Ridder (1997) note that some methodological limitations may be a reflection of conceptual uncertainties. Therefore, assessment of the suitability of the finer detail of scenario based tools in terms of their imaginability, threatfulness, controllability and predictability is essential (Krohne and Egloff, 2005; Bijttebier et al., 2001). The use of hypothetical versus real life situations scenarios centres around issues of validity. Endorsing items pertaining to the same scenario enhances comparability however, they must be sufficiently familiar to enable the individual to imagine themselves confronted with the situation (Muris et al., 1994). Secondly, the degree of stressful appraisal, that is harm, loss, threat or challenge required to elicit a coping response is a matter of contention (Schwarzer and Scwarzer, 1996; Muris and De Jong, 1993). Responses to threat are more likely to induce avoidant coping mechanisms, whereas challenge is associated with positive reappraisal (Bijttebier et al., 2001). The juxtaposition to this is that individuals with high monitoring coping styles are more likely to perceive a situation to be threatening than those with a low monitoring style (Muris and De Jong, 1993). Thus, the monitoring style may influence the appraisal of the situation as well as coping behaviour, that is, a chicken and egg situation. Thirdly, coping is said to be influenced by the controllability and predictability of the situation (Miller, 1981). High controllability and predictability of an adverse event is associated with effective monitoring. However, monitoring is of no instrumental value in low controllability and predictability situations, when blunting becomes the favoured mode (van Zuuren et al., 1996). A high degree of variability of control and prediction across scenarios may therefore minimise situational effects. Conversely, Bijttebier et al. (2001) suggest that comparable scenarios may be associated with stable coping responses, whereas dissimilar situations may result in greater variation of coping response. Finally, monitoring strategies have been clearly described in terms of sensory vigilance. That is, a ruminant focus upon the threat and active information seeking such as questioning. Thus, monitoring item measures are clear, distinguishable and allow for content analysis across various scales. In comparison, blunting refers to partial or complete avoidant behaviours however there is a lack of conceptual clarity in the literature (Bijttebier et al., 2001). These factors influenced the choice of informational coping assessment tool for this study.

The Miller Behavioural Style Scale (MBSS) (Miller, 1987) was designed to measure levels of monitoring and blunting in the context of general life threatening situations. The MBSS was subsequently re-designed and validated to assess threatening medical scenarios by van Zuuren and colleagues. The Threatening Medical Situations Inventory (TMSI) (van Zuuren et al., 1996; van Zuuren and Hanewald, 1993), a self-report questionnaire which assesses monitoring and blunting styles in the domain of medical threat was selected. It has been used in several cancer treatment decision making studies (Rood et al., 2015; Roussi and Miller, 2014; Wakefield et al., 2007; Timmermans et al., 2007; Ong et al., 1999; van Zuuren et al., 1996; van Zuuren and Hanewald, 1993). The original TMSI includes four imaginary medical scenarios portraying varying degrees of controllability and predictability. They were suspicious headache, hypertension, uncertain cardiac surgery and appendicitis. The scenarios were followed by six statements concerned with how one might cope with the situation. Three statements represent ‘monitoring’; an active style of information gathering and three ‘blunting’ or information avoidance. Each scenario requires a response on a 1 (not at all applicable) to 5 (strongly applicable) Likert scale to the randomly ordered monitoring and blunting statements, with 24 items in total (van Zuuren et al., 1996; van Zuuren and Hanewald, 1993). The five point rather than dichotomous scale was selected to provide greater variability in the data and thus improve reliability (Bijttebier et al., 2001).

The TMSI has acceptable to good internal consistency for the monitoring (r>0.75 - 0.84) and blunting (r>0.62 – 0.80) scores across different sample groups (Wakefield et al., 2007; van Zuuren et al., 1996; van Zuuren and Hanewald, 1993; Timmermans et al., 2007; Ong et al., 1999). It has good correlations with monitoring and blunting dimensions of the MBSS (Muris et al., 1994) and Cronbach's Alpha reliability analyses has shown a coefficient of 0.82 for both monitoring and blunting (Bedi and Brown, 2005; van Zuuren and Dooper, 1999). A valid and reliable abbreviated (two of four scenarios) version has subsequently been used among cancer patients demonstrating good internal consistency, Cronbach's α ranging from 0.72 to 0.77 for monitoring and 0.62 to 0.79 for blunting (Vosbergen et al., 2014; Timmermans et al., 2007; Sheehan et al., 2007; Ong et al., 1999). Krohne (1989) advised the inclusion of a sample specific scenario and more recently, a modified short TMSI incorporating a disease specific scenario had been successfully employed (Rood et al., 2015). Participants in this study were therefore presented with an adapted TMSI which included three of the original scenarios (van Zuuren et al., 1996; van Zuuren and Hanewald, 1993). The fourth relating to appendicitis and impending surgery was substituted with a CRMD specific decision scenario (Supplementary Information 5. Question 25) to improve the relevance of the questionnaire for this group. Rood et al. (2015) do not clarify how they developed their additional scenario. Therefore, the scenario wording was closely based upon the original, while substituting the symptoms and intervention for appendicitis with those associated with chronic heart failure and CRT implantation. The original response format was maintained. A reliability analysis was performed to assess the internal consistency and reliability of the monitoring subscale and the CRMD scenario. Cronbach's alpha showed that the monitoring subscale consisting of 12 items had a strong internal reliability coefficient of $\alpha=0.89$. Cronbach's α decreased when each of the three items specific to the CRMD scenario were deleted, meaning that the scenario was worthy of retention.

Various methods of scoring the TMSI for analysis have been documented. In early studies, the sum of monitoring statements across the four scenarios (TMSI-M) was established independently of the blunting scores (TMSI-B), with total scores ranging from 12 to 60 (van Zuuren et al., 1996). Some researchers compared monitoring and blunting scores (Ong et al., 1999) and others reported total monitoring scores only (Muusses et al., 2012; Meulenkamp et al., 2010). van Zuuren et al. (1996) concluded that the blunting coping style was independent of monitoring. Furthermore, results obtained from the monitoring subscale are reported to be stronger and more reliable predictors of patient preferences than reliance upon the blunting sub scale (Bijttebier et al., 2001; van Zuuren et al., 1996; Miller et al., 1988). Therefore, coping style in terms of information gathering was reported and analysed as levels of monitoring (not blunting) in keeping with the theoretical focus of this study. The decision to treat measures such as monitoring taken at an ordinal level (the Likert scale), as ordinal or interval remains controversial (Knapp, 1990). For this study, a pragmatic approach was adopted on the basis that an underlying interval continuum from low to high monitoring was present and the resultant data was normally distributed, therefore justifying parametric testing.

Some studies, such as Shiloh et al. (2008) also refer to low and high monitoring sub groups though there is little detail or consistency regarding the method of distinction between the groups. As thresholds for high and low monitoring have not been published, the sample mean provided the cut-off point in this study. Scores above the mean were categorised as high monitors and below the mean as low monitors. High low monitoring categories were established to facilitate odds ratio calculations. As a result of the method used to categorise high and low monitors, these findings can only be applied to this sample.

4.2.3.3 The Decision Approach

This study was particularly interested in whether the level of monitoring translated into systematic information gathering in the context of CRMD recommendation. Section 6 was interested in the participants approach to decision making. The notion that when individuals are faced with uncertainty and choice, they employ two processes, effortless, automatic heuristics and effortful, conscious systematic information processing is not disputed (Kahneman, 2011; Gigerenzer and Todd, 1999; Chen, S. and Chaiken, 1999). Attempts to identify, measure and isolate the operation of heuristics in decision making is beyond the scope of this project and can be found elsewhere (Bellur and Sundar, 2014).

This study sought to differentiate between the use of heuristic and systematic information processing and determine whether specific factors such as monitoring might predict a patients predilection towards one or both. It is commonly accepted that patients will readily access information from the experts (doctors and nurses) at the point of recommendation (Muusses et al., 2012). The main decision approach was therefore judged by the level of engagement with source and type of additional information seeking pursued. Question 26 asked participants to indicate if and where they had sourced further information following the device recommendation.

Participants who appeared to be satisfied with the verbal and written information received from the consultant and/or specialist nurse only, were described as ‘expert opinion’ heuristic information gatherers i.e. reliant upon expert opinion. Those who stated that they had sought advice from a partner, family member, friends or patients with a device were grouped as ‘expert and availability’ heuristic information gatherers. For analytical purposes, both groups were then categorised as predominantly heuristic information gatherers. Participants who, in addition to the above, indicated that they had also gleaned advice from other sources such as GP and searched and accessed further information from general websites including google, patient forums and/or professional websites such as NICE and BHF were described as active, ‘systematic’ information gatherers. The accuracy of gleaning this type of information from questionnaire cannot be guaranteed and could introduce an element of bias into the findings. However, Strand 2 allowed further exploration of individual information gathering to compare and so substantiate the survey data.

4.2.3.4 Decisional Control Preference (DCP)

The Decisional Control Preferences (DCP) Scale (Degner et al., 1997a; Degner et al., 1997b) was included as a clinically relevant, easy to administer, valid and reliable measure of preferred and actual roles in healthcare decision making, as it has been extensively referred to in the general decision making literature (Tariman et al., 2010). The five statements, detailed in Table 4.2, reflect the concepts of decision making described by Charles et al. (1999). They described patterns of collective decision making from pure consumerist, informative and active (A) to pure paternalist, passive (E). Pure shared, collaborative decision making represented a central point between the two (C). As such, the scale corresponds well to Charles et al conceptual framework for this study. Q 28 asked participants to rank the order in which five items, ranging from active to passive, described their preference for decision making regarding device therapy on a 1 (most preferred) to 5 (least preferred) scale (Table 4.2). They were advised to provide a different number between 1 and 5 for each statement. NB Letters A to E were not visible on the participant questionnaire.

The intention of the scale was to determine the order in which participants rated their desired level of control over their decision making and thus assign an ordinal category to the rank order, as designed by Degner et al. (1997b). Degner et al. (1997b) validated eleven possible combinations of score selection and assigned an ordinal number from 1 to 11 to them. Therefore, A, B, C, D, E would receive an ordinal figure of 1 indicating a desire for the highest degree of control in decision making. B, A, C, D, E would receive a figure of 2. Similarly at the opposite end of the scale those who ranked their control preference as E, D, C, B, A were assigned a figure of 11 indicating the lowest reference for decision making and D, E, C, B, A received 10 as the next outermost score.

Table 4-2 Preferred Decisional Control Question 28 Of The Participant Questionnaire

Q. 28	I prefer to:		
	A	Make the final selection about which treatment I will receive	
	B	Make the final selection of my treatment after seriously considering my doctor`s opinion	
	C	Have my doctor and I share responsibility for deciding what treatment is best for me	
	D	Have my doctor make the final decision about which treatment will be used, but seriously considers my opinion	
	E	Leave all decisions regarding my treatment to my doctor	

The Control Preference Scale (Degner et al., 1997b) - Adapted with permission

Despite extensive use of the DCP in the patient treatment decision-making literature, reporting of acceptable psychometric properties (De las Cuevas and Peñate, 2016; Kremer and Ironson, 2008) and a good response from the pilot test, this question was not always answered in the manner requested. Rather than rating the order which reflected most to least preferred option, many participants selected just one or two of the statements. It is difficult to determine why there was some variance in the way that participants completed this question. As it featured on the penultimate page 49 of the questionnaire, it is conceivable that a waning level of concentration may have influenced interpretation of the instructions for the question. That said, selection of the most preferred option had been previously described as a valid alternative to the ranking options method (Neufeld et al., 1993). On reflection, opting for this method in the first instance may have enabled more simplified instructions to be given and avoided the inconsistencies noted.

The most preferred option, regardless of how the question was answered was therefore accepted. However this posed further challenges for the application of Degner’s eleven stage ordinal scoring system. Consequently, Degner’s scoring system was simplified by collapsing the eleven possible scores from selection of statements in rank order to a score of 1 to 5 for each corresponding statement (Table 4.3). The selected statement was taken to indicate their main preference and scored on the 1 to 5 scale accordingly. If participants ranked the options from 1 to 5, the statement they had assigned as 1 was scored on the ordinal scale. If they had selected more than one preferred options; AB or DE they were assigned to the least extreme numerical value from 1 to 5 resulting in a preference for active, collaborative or passive decision making.

Table 4-3 Adapted Decisional Control Preference Scoring System

	Most Favoured Response	**Charles et al (1999) Descriptors**	**Assigned Ordinal Score**
A	Make the final selection about which treatment I will receive	Active, active	1
B	Make the final selection of my treatment after seriously considering my doctor`s opinion	Active, collaborative	2
C	Have my doctor and I share responsibility for deciding what treatment is best for me	Collaborative	3
D	Have my doctor make the final decision about which treatment will be used, but seriously considers my opinion	Passive collaborative	4
E	Leave all decisions regarding my treatment to my doctor	Passive, passive	5

Participants also selected the one item which most closely corresponded with their actual level of involvement, in order to determine whether a match between desired and actual levels of involvement occurred (Table 4.4). Again the letters A to E were not visible on the participant questionnaire. Ordinal scores of 1 to 5 were assigned to the A to E statements to provide a score as indicated by the respondent.

Table 4-4 Actual Decisional Control Question 30 Of The Participant Questionnaire

Q. 30	A	I made the final decision about device implantation	
	B	I made the final decision about device implantation after seriously considering my doctor`s opinion	
	C	My doctor and I shared responsibility for deciding whether I should have device implantation	
	D	My doctor made the final decision about device implantation, but seriously considered my opinion	
	E	I left the final decision regarding device implantation to my doctor	

4.2.3.5 Decisional Regret

The Decisional Regret Scale (Brehaut et al., 2003) a short, straightforward scale to measure the experience of regret with a decision as an indicator of decisional satisfaction was selected as it has also been used previously (Hickman, 2010; Hawley et al., 2008). The five item scale requires a 1 (strongly agree) to 5 (strongly disagree) score against each item, with total scores ranging from 5 to 25. The average score is converted to a 0 (no regret) to 100 (high regret) score, by subtracting 1 and multiplying by 25. The scale has good reported internal consistency (Cronbach's = r>0.81 – 0.92), and it correlates strongly with decision satisfaction (r= –0.40 to –0.60), decisional conflict (r= 0.31 to 0.52), and overall rated quality of life (r= –0.25 to – 0.27) (Sheehan et al., 2007; Brehaut et al., 2003; O'Connor, 1996). Exploratory and confirmatory factor analyses, internal reliability consistency (= 0.86) and discriminant validity, established the decision regret scale (DRS) to be a valid and reliable measure of decision regret among ICD recipients (Hickman Jr et al., 2012). It has been used in other ICD decision-making studies (Green et al., 2016). The questionnaire concluded with an invitation to participate in Strand 2 interviews, at a convenient time and place to coincide with the next clinic appointment.

4.2.4 Survey Pilot Testing

In order to establish the overall validity of the questionnaire, a draft survey was pilot tested among a group of ICD recipients attending a post implant support group. Nineteen completed the paper version and 6 online allowing clarification, minor amendment and confirming the time required to complete. Feedback was positive and informed some minor adjustments. For example, contact details were originally asked for at the beginning of the questionnaire but this was considered to be unnecessary duplication and so was removed. Some brief explanatory statements at the beginning of each section were added and some questions were expanded with examples. Lastly, the predicted time to complete was increased from 10 minutes to 15 to 20 on all documentation to accommodate the slower completers. Those who completed online reported it taking much nearer 10 minutes, however the same instructions were included in both versions for consistency. Otherwise, despite the issues related to question 28 described above, the service user pilot group were confident in completion and understood the rationale for the different sections, confirming overall validity of the questionnaire.

4.2.5 Ethical Considerations

Healthcare research must be conducted in an ethical manner to safeguard and protect the privacy and rights of human subjects (Gray, J., 2017). This requires due consideration of the key pillars of medical ethics and issues particular to this study. The NHS Health Research Authority (HRA) and incumbent Research Ethics Committees (REC), are responsible for national governance of healthcare ethics. Local Research and Development (R&D) approval ensures governance, capability and access. Therefore, appropriate guidance for this study was followed https://www.hra.nhs.uk. Application for HRA ethical approval and subsequent research governance approval from each Trust commenced in February 2016 (IRAS Project Id 194017). HRA approval was promptly granted in July 2016 (Appendix J). Gaining access to relevant sites was slow but eventually issued between January and May 2017 (Appendix K). In response to slower than expected recruitment, HRA and R&D approval was sought and granted to approach a fifth participant identification centre (PIC) site in February 2018 (Appendix L). Ethical approval was granted on the basis of the following conditions.

4.2.5.1 Informed Consent

Respect for the right to self-determination and autonomous choice is embedded in the process of informed consent. This relies upon participant comprehension of sufficient, relevant, honest information and voluntary expression of consent. To avoid undue pressure, potential participants were approached after the consultation at which they had reached their decision by a member of the direct care team at each implant centre. Participants were offered a brief explanation and 'request permission for PI to contact' information sheet[4i or 4ii]. Complete participant contact forms were either posted, e-mailed or left in the clinical area for the PI to collect. To avoid introducing additional influence into the decision making process, participants were not formally approached by the PI until the device had been implanted or for those who declined, after they had consulted with a Doctor and/or ICD nurse. Implant dates were verified via the pre-assessment nurse or admissions secretary to ensure that this occurred. On receipt of permission and an agreed mode and time to contact, the PI explained the purpose of the two strand study. Participants were advised that they could participate in one or both strands of the study. For Stand 1, a study pack, including cover letter[4iii], participant information sheet (PIS)[4iv], questionnaire and SAE were mailed electronically or by post at the agreement of the recipient. Instructions on how to access alternate online completion were included. PI contact details were included and participants advised to make contact should they require any further information. Participation was voluntary and consent for Strand 1 assumed on return of the questionnaire at the participants convenience. In the interests of achieving optimal recruitment targets, permission to contact non-responders on one occasion after 4 weeks was also obtained.

4.2.5.2 Confidentiality, Anonymity And Data Storage

The Caldecott Principles (Department of Health, 1997) and GDPR (2018) guidance were adhered to throughout. All potential participants received a PIS explaining the study, the details and extent of their involvement and assurance that all information

4i and 4ii Permission To Contact Request Forms, 4iii Cover Letter and 4iv PIS are available in the supplementary information.

would be anonymised and remain confidential. Participant details and survey data were anonymised on receipt using a combination of letter and number (PIN*).* Data was stored in line with the university Code of Practice on Data Protection http://www.leeds.ac.uk/secretariat/data_protection_code_of_practi ce.html. Participant identification information and survey data was stored electronically in password protected files on the secure drive at the University of Leeds and only accessed by the PI. Paper documentation, including questionnaires, consent forms and additional field notes remained confidential. They were stored in a locked filing cabinet in a locked room on the University of Leeds campus. The Bristol Online Survey (BOS), was selected for provision of an online version of the questionnaire. It was considered to be a secure online survey facility provided by the University of Bristol, UK and was supported by the University of Leeds. Functionality allowed survey access control. Data access was strictly limited to the BOS support and technical team at the request of the PI only. Data processed by BOS operations was transferred in to a password protected file on the secure drive at the University of Leeds for further statistical analysis. Data will be kept for no longer than 5 years post successful submission of the thesis. It will be destroyed as confidential waste and electronic files permanently deleted from the secure drive and BOS server.

4.2.5.3 Risks, Burdens And Benefits To Participants

While low in risk, self-selection ensured that any potential risks and benefits of study inclusion were fairly distributed. Time invested by participants to complete the questionnaire could be construed as inconvenient. Questionnaires were therefore completed at the participant’s leisure. A hard copy and on line version were made available to all potential participants. Instructions on access and completion of the online version was included on the hard copy of the questionnaire. A pilot test of questionnaire completion by a support group of device recipients prior to the study confirmed that the questionnaire should take no more than 20 minutes to complete. Participants were informed (PIS) that there would be no direct benefit from involvement. It is conceivable that some may derive personal satisfaction from the opportunity to share their experience and opinions. Equally a sense of having made a potential positive contribution to the healthcare of future patients may be considered to be beneficial for some.

4.2.5.4 Right To Withdraw

Participants were advised (verbally & PIS) that they could withdraw their involvement from Strand 1 up to 2 weeks after submitting their completed questionnaire without giving reason. Once this period had expired their anonymised responses would have been included in the analysis and could not be withdrawn. Ethical issues specific to Strand 2 are detailed in Chapter 6.

4.2.6 Quantitative Data Analysis

The Strand 1 data set was initially analysed independently of Strand 2 (Simons and Lathlean, 2010; Teddlie and Tashakkori, 2009). Questionnaire scoring tables[5] were developed and applied to the survey data prior to loading into the latest version of the IBM SPSS Statistics software (v25). Data types were identified. Multi response questions such as medical history, alternative options, device knowledge and information sources were assigned yes, no, don’t know or missing values.

Frequency, central tendency and dispersion was described for each element of the questionnaire data and bar charts, pie charts, histograms, box and scatter plots were used to illustrate findings as appropriate. A range of inferential tests was selected on the basis of data type, normality of distribution and the number of variables, to test respective differences in categorical and continuous, demographic and clinical variables between participants. Access to an adequately large sample is essential to enable true relationships between variables to be realised and avoid inaccurate effect size estimation (Shadish et al., 2002). However, the resultant sample size (n=50) fell short of the power calculation which presented challenges for the planned analytical strategy. Strategies to moderate this are described, however findings must be considered with some caution. Failure to reject a null hypothesis could indicate a lack of relationship between variables or it could represent a type II false negative error and inability to detect a difference due to the small sample size (Gray, J. et al., 2017). For example, cross tabulation was used to describe the bi-variate and multi-variate distribution of categorical data sets such as gender or age category and decision approach. Pearson’s Chi Square (χ^2) was performed to assess for the presence of an association. Due to the small samples in this study some cells frequently had a count of <5 and therefore the asymptotic *p*-values given for a true Chi-square may be misleading. Yate’s continuity correction adjusts the formula for Pearson's chi-squared test (reduces χ^2 and increases *p* values) to prevent overestimation of the statistical significance for small data. However, its potential for overcorrection can result in type II errors (failure to reject the null hypothesis when it should). It is therefore suggested that Yates's correction is unnecessary even with low sample sizes (McDonald, 2014). Furthermore, some tables had more than two columns therefore Yate’s would not be

[5] Questionnaire Scoring Tables are available in the supplementary information.

applicable and finally the Yate's test is not an available function of SPSS. Therefore, conscious of erring on the side of caution Fisher's exact *p*-values were requested and reported for every Chi-square test. For 2x2 contingency tables, Phi and Cramer's V strength of association tests were applied if appropriate.

Interval (scale) data was described using histograms and / or scatterplots and assessment of distribution curves, proximity of standard deviations (SD) and Kolmogorov-Smirnov and Shapiro-Wilk tests of normality were undertaken. A significant value $p>0.05$ confirmed that the data was normally distributed whereas a $p<0.05$ indicated that the data deviated significantly from the normal distribution. When assumptions of normality could not be met, non-parametric tests were undertaken. For comparison of means between interval and nominal data, independent samples *t* test and ANOVA (*F*) or their non-parametric equivalents, Mann Whitney *U* and Kruskall Wallis tests were applied. If Levene's test statistic was $p>0.05$, the assumption of homogeneity of variances was confirmed and the result of the *t* test in the equal variances column was accepted. Pearson's correlation (*r*) was used to explore normalised interval data to determine whether a linear relationship exists between two variables. If so, the strength of the association (effect size) was measured by the coefficient of determination r^2 and classified according to Cohen's guidelines (Cohen, 1988)[6]. To accommodate the small sample sizes involved, the degrees of freedom of the regression estimate can be applied to adjust the value of r^2 down in an effort to eliminate its positive bias. Thus, the adjusted r^2 is reported.

Where a correlation was suspected, simple and multiple linear regression techniques were applied to determine the predictive value of the dependent variable from the independent variable(s). Again, the sample size recruited did not entirely meet the conditions required for multiple regression. The recommended number of events per variable varies from 5 to > 50 in the literature (Harrell, 2015). Yet future combination of this and other small studies could provide a larger more powerful analysis, therefore judicious use of regression analysis techniques were considered to be worthwhile. Ideally, all variables that are known to affect the outcome should be included in the model. Exclusion of non-significant variables at univariate analysis could overcome sample size issues but at the expense of introducing bias. Indeed, variable selection approaches based upon univariate statistical significance are commonly applied in practice (Rood et al., 2015; Michel et al., 2011). However, it risks excluding some variables that may become significant in multivariate analysis and statistical theory to justify this technique is lacking (Heinze and Dunkler, 2017).

[6] Cohen's Classification Of Strength Of Association Tables are available in the supplementary information.

Based upon previous studies such as Meulenkamp et al. (2010), the decision to exclude variables that lacked heterogeneity from the model, and use backward elimination to sequentially remove non-significant predictors from the multivariable model was taken. Thus, resulting in a re-estimated model based upon variables that have a significant association with the outcome (Heinze and Dunkler, 2017; Meulenkamp et al., 2010).

Other preconditions for regression modelling refer to linearity, multicollinearity and homoscedasticity (Gray, C. and Kinnear, 2012). The significance of the regression ANOVA (F) was used to support the assumption of linearity between the variables. The unstandardised regression coefficient, β_1 is given to indicate the slope of the regression line and residual diagnostics were performed to ensure that the necessary conditions for linear regression modelling were met. A tolerance index of < 0.10 and variance inflation factor (VIF) close to 1 or below 5 was accepted evidence of absent collinearity issues. Scatterplots of standardised residuals and standardised predicted values were produced. A shapeless scatter with equal distribution of data above and below the horizontal line at zero confirmed homoscedasticity, indicating that the linear regression model was appropriate for the data and so indicate the accuracy of the estimates gained.

Logistic regression was substituted to assess categorical and or continuous predictors against dichotomous categorical dependent variables. Odds ratio was performed with dichotomous dependent and independent variables. Logistic regression does not rely upon assumptions regarding the data type, distribution of predictor variables or linearity (Grove and Cipher, 2017), however as with linear regression, sample size was a limiting factor. To accommodate this, and improve the power and ease of statistical interpretation, Hosmer and Lemeshow (2000) advocate that the number of cases in the smallest group be ten times the number of predictors. Thus, the number of variables entered in to the model was generally limited to four. Two tailed p values and a pre-set level of significance of $p<0.05$ to accommodate the small sample size are referred to throughout.

4.3 The Findings

The key findings are organised and presented in response to the Strand 1 aims and objectives identified. Of 73 potential participants approached, 50 (68.5%) returned a completed survey (Table 4.5). Twenty two (44%) were recruited from site ‘L’, 13 (26%)

from ‘S’, 13 (26%) from ‘W’ and 2 (4%) from site ‘C’. Seven different consultants cared for the L patients, 3 for S, 4 for W and 2 for C.

Table 4-5 Survey Response Rate

Reasons Given	**C**		**L**		**S**		**W**		**Total**
	M	**F**	**M**	**F**	**M**	**F**	**M**	**F**	
Complete survey returned	2		17	5	10	3	13		50
Do not wish to participate					2		1	2	5
Survey not returned, no explanation	1		2		3		4	1	11
Incorrect or insufficient contact details provided			2		1				3
Too unwell therefore implant cancelled					1				1
Complications post implant requiring further intervention			1			1	1		3
Total	**3**		**22**	**5**	**17**	**4**	**19**	**3**	**73**

Although a low survey response rate is common, a relatively small number, 23 (31.5%) did not participate, despite providing initial permission to contact. The non-responders included 19 men and 4 women. The permission to contact form requested a mode of contact only, therefore more detailed demographic data was not available. As the non-responders had not consented to participate, ethically it was not feasible to request further information from medical records to determine whether the study had attracted a biased sample. What was known was that nine actively declined to participate, either without reason or due to their current health condition. Eleven failed to return the questionnaire despite the polite reminder and 3 were uncontactable. One participant who had initially declined the interview at first contact, returned a survey that was too incomplete to include. This does present the potential for a biased sample and therefore results can only be truly applied to this study cohort with confidence.

4.3.1 Socio-demographic Characteristics

The socio-demographic details of fifty participants who completed the survey are shown in Table 4.6. There were 42 (84%) men and 8 women with an overall mean age of 66.4 years ± 11.67, ranging from 34 to 82 years. The slightly lower mean age of women was not statistically significant. As the mean age equates to the current approximate retirement age, it was used to differentiate between ‘younger’ (32 to 65 years; n=21) and ‘older’ (66 to 82 years; n=29) adults, to aid further analysis and distinguish where, if any age difference occurred. This sample was relatively homogenous with 49 (98%) identifying themselves as White British and either Christian (78%) or of no religious persuasion (20%) limiting opportunity to explore ethnicity or religion as a factor. Levels of social support were established by combining marital status and proximity of next of kin. 41 (82%) were married or civilly partnered and lived with their next of kin.

Table 4-6 Socio-demographic Characteristics Of The Participants

Characteristics	n	%	Mean	Standard Deviation
Gender				
Male	42	84		
Female	8	16		
Age (Yr)*			66.40	11.67
Male			67.43	10.83
Female			61.25	15.19
Ethnicity				
White (British)	49	98		
Mixed White & Asian	1	2		
Religion				
Christian	39	78		
Buddhist	1	2		
None	10	20		
Marital Status				
Single	4	8		
Married / Civil Partner	41	82		
Separated / Divorced	3	6		
Widow/er	2	4		
Social Support				
Lives With Next Of Kin	41	82		
Next Of Kin Nearby	3	6		
Lives Alone, Friends Nearby	6	12		

Table 4.7 illustrates the levels of education, categorised according to the number of reported years in formal education and occupational status. There were no reported students and all participants had either ticked the applicable occupational status box or had stated their job title in the ‘other’ text box, allowing an occupational status to be assigned. In the latter cases, an academic supervisor independently assigned an occupational status confirming the accuracy of the assessment. A combination of educational level and occupational status was used to provide a crude estimation of aptitude for health literacy (HL) as described in table 4.1.

Table 4-7 Levels Of Education And Occupational Status

Characteristics	n	%	Mean Age	SD	Test statistic df; *p* level
Education (No Of Years)					
< 11 years (Secondary Ed, ‘O’ Level, GCSE)	24	48	69.50	9.29	*F*=2.31; df=2; *p*=0.13
11-13 years (‘A’ Level, Cert / Diploma)	15	30	65.47	11.34	
> 13 years (Degree/ PhD)	11	22	61.09	15.29	
Occupational Status					
Student	0	0			
Unskilled Manual	8	16	68.00	10.03	*F*=2.73; df=4; ***p*=0.04****
Semi-Skilled Manual	12	24	70.25	8.23	
Clerical	4	8	58.75	10.01	
Managerial	19	38	68.84	11.08	
Professional	7	14	56.00	15.36	
Employment Status					
Employed / Self Employed	15	30	56.20	11.91	*F*=10.12; df=3; ***p*=0.001****
Retired	33	66	71.67	7.96	
Seeking Employment	1	2	56.00		
Unemployed	1	2	58.00		
Volunteer	0	0			
Estimated Aptitude For Health Literacy (HL)					
Lower Aptitude	21	42	68.90	8.82	*t*=1.28; df=48; *p*=0.21
Higher Aptitude	29	58	64.66	13.23	

F = ANOVA statistic df =Degrees of freedom
p = Significant at <0.05 ** = Significant

There was a non-significant inverse relationship between age and years in education. Participants in the clerical and professional groups were significantly younger than those with an unskilled or semi-skilled and managerial occupation. Less than 11 years in formal education was associated with being unskilled and semi-skilled and more than 13 years with professional groups. As expected the retired group were significantly older than those in or seeking employment. Two HL groups were categorised as lower aptitude (21; 42%) and higher aptitude (29; 58%). The mean age of those with a lower aptitude (68.90, SD 8.82) was not significantly different to participants in the higher aptitude (64.66, SD 13.23) group (*p*=0.21). Figure 4.2 and 4.3 illustrate the relationship between gender, age category and aptitude for health literacy scores. There were an equal number of women (4, 50%) in each HL aptitude category. Seventeen men (40.5%) were categorised as lower aptitude for HL compared with 25 (59.5%) men in the higher aptitude group. When participants were categorised according to younger or older age groups, there was a higher proportion of the younger group in the higher aptitude for HL group (n=14) than in the low aptitude group (n=7). Whereas, there were even numbers of the older age group in each HL group (Table 4.8).

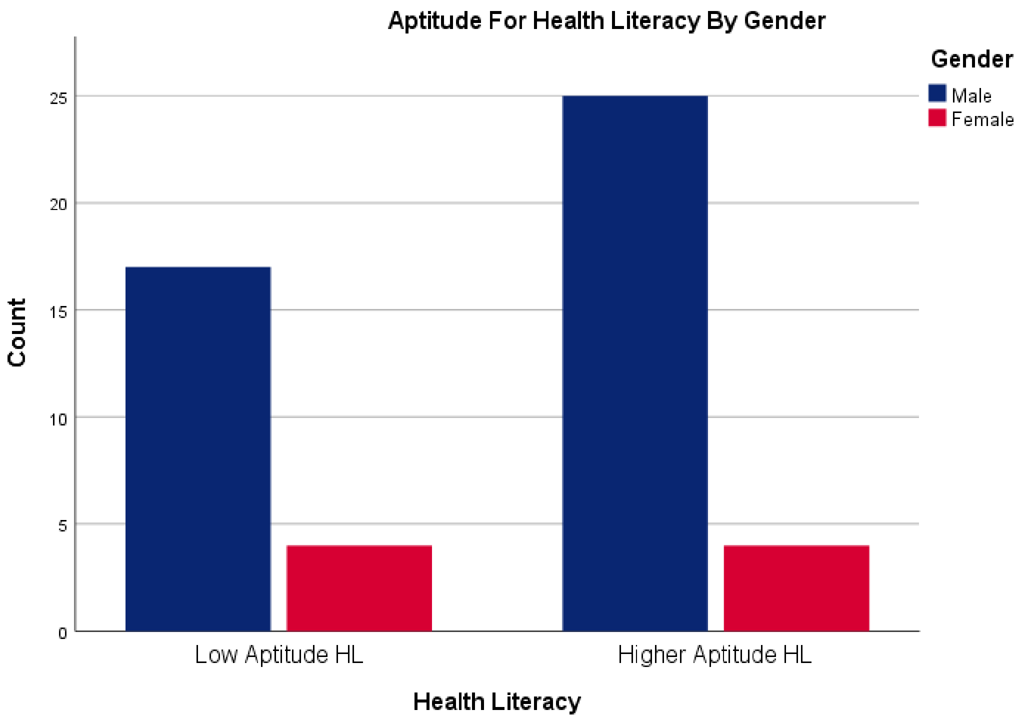


Figure 4-2 Aptitude For Health Literacy By Gender

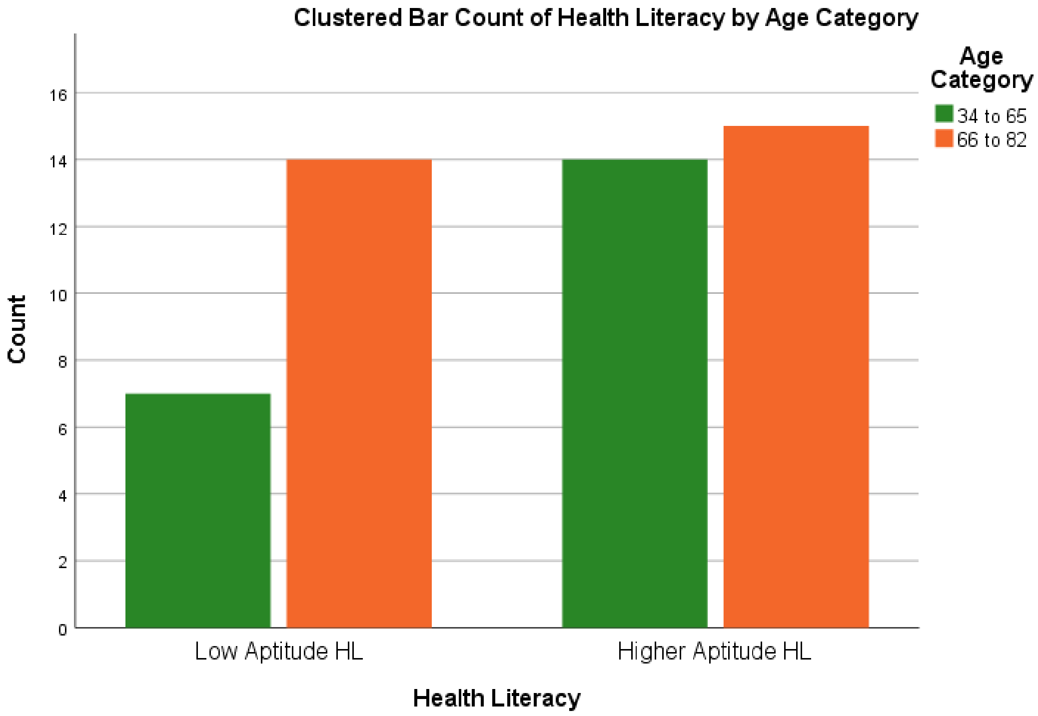


Figure 4-3 Health Literacy By Age Category

Pearson Chi-Square did not reveal a relationship between HL scores and gender (χ^2=0.25; df=1; *p*=0.71) or age category (χ^2=1.12; df=1; *p*=0.39) (Table 4.8). Mann Whitney *U* tests corroborated this finding (gender *p*=0.85; age groups *p*=0.16).

Table 4-8 Estimated Health Literacy By Gender And Age

	Lower Aptitude (% within group)	**Higher Aptitude** (% within group)	Test statistic df; *p* level
Gender			
Male	17 (81)	25 (86.2)	χ^2 0.25; df=1; *p*=0.71
Female	4 (19)	4 (13.8)	
Total	21 (100)	29 (100)	
Age Category			
34 – 64	7 (33.3)	14 (48.3)	χ^2 1.12; df=1; *p*=0.39
65 – 82	14 (66.7)	15 (51.7)	
Total	21 (100)	29 (100)	

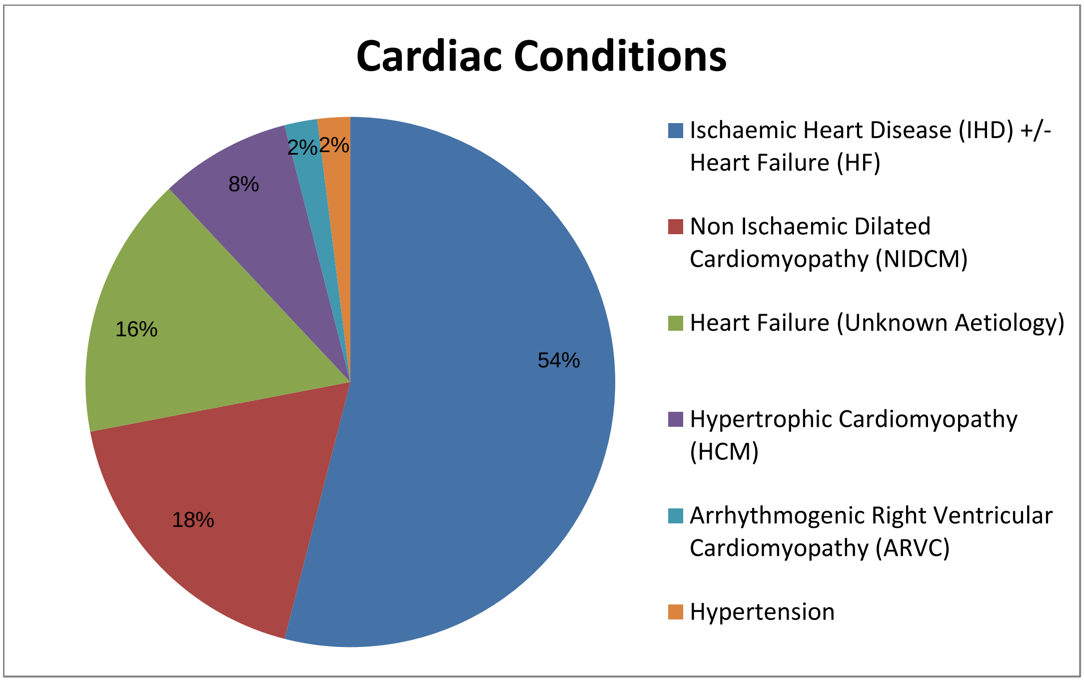
χ^2 = Pearson Chi-square statistic NB Some cells had an expected count <5 . Fisher's exact *p* values reported
df =Degrees of freedom
p = Significant at <0.05

4.3.2 Situational Characteristics

4.3.2.1 Cardiac Condition And Severity

Participants described their cardiac condition in variable detail (Figure 4.4). Twenty seven (54%) participants had evidence of ischaemic heart disease (IHD). That is, myocardial infarction (MI) and/or ischaemia (angina) and/or ischaemic dilated cardiomyopathy (IDCM) ± heart failure (HF). Nine (18%) stated cardiomyopathy with an undisclosed cause and so were labelled as non-ischaemic dilated cardiomyopathy (NIDCM) ± HF. Four (8%) had inherited hypertrophic cardiomyopathy (HCM) ± HF and one (2%) arrhythmogenic right ventricular cardiomyopathy (ARVC). Eight (16%) men stated heart failure (HF) but did not indicate any other underlying cause. One other older male who only indicated hypertension had received a CRT-D and so was classified as HF.

Figure 4-4 Self-Reported Cardiac Conditions



Participants were less clear about whether they had a rhythm disorder and if so what type. Many answered 'don't know' for one or more of the rhythm questions. Of twenty seven (54%) who had experienced tachyarrhythmia, four did not state the site of origin. Sixteen (32%) described supraventricular arrhythmias, most commonly atrial fibrillation (AF), five (10%) had ventricular arrhythmias and one (2%) had experienced both. Twelve (24%) also reported episodes of bradycardia which were often drug induced and did give rise to unwanted symptoms. Younger participants (<66 years) appeared more likely to report VT/VF (χ^2=6.04; df=2; *p*=0.05) than the older group, otherwise there was no evident relationship between arrhythmia history, gender and age (Table 4.9).

Known IHD affected a higher proportion of men (57%) than women (37.5%), but the gender difference was not significant (χ^2=1.04; df=1; *p*=0.44) (Table 4.9). Seventy percent (n=19) of those with known IHD were in the older (>65) age group (χ^2=3.69; df=1; *p*=0.09). Conversely all those with inherited cardiomyopathies were in the younger group (χ^2=3=7.67; df=1; *p*=0.01). Two participants reported congenital structural cardiac defects (ARVC and aorto-annular ectasia). Channelopathies such as Long QT, Brugada syndrome were not apparent.

Table 4-9 Relationship Between Cardiac Condition, Arrhythmia History, Gender And Age

	Known IHD[I] n (%within group)	Test statistic *p* level	**NIDCM**[II] n (%within group)	Test statistic *p* level	**HCM/ ARVC** n (%within group)	Test statistic *p* level	**HF**[III] n (%within group)	Test statistic *p* level	**VT / VF**[IV] n (%within group)	Test statistic *p* level	**SVT**[IV] n (%within group)	Test statistic *p* level	**Brady**[V] n (%within group)	Test statistic *p* level
Gender														
Male	24 (88.9)	χ^2 1.04; df=1; *p*=0.44	6 (66.7)	χ^2 2.45; df=1; *p*=0.14	3 (60)	χ^2 2.38; df=1; *p*=0.18	9 (100)	χ^2 2.09; df=1; *p*=0.32	5 (83.3)	χ^2 1.02; df=2; *p*=0.62	15 (88.2)	χ^2 0.73; df=2; *p*=0.79	10 (83.3)	χ^2 0.79; df=2; *p*=0.70
Female	3 (11.1)		3 (33.3)		2 (40)		0		1 (16.7)		2 (11.8)		2 (16.7)	
Total	27 (100)		9 (100)		5 (100)		9 (100)		6 (100)		17 (100)		12 (100)	
Age Category														
34 – 65	8 (29.6)	χ^2 3.69; df=1; *p*=0.09	5 (55.6)	χ^2 0.83; df=1; *p*= 0.46	5 (100)	χ^2 7.67; df=1; **_p_=0.01****	3 (33.3)	χ^2 0.34; df=1; *p*=0.72	5 (83.3)	χ^2 6.04; df=2; **_p_=0.05****	6 (35.3)	χ^2 0.48; df=2; *p*=0.82	5 (41.7)	χ^2 0.11; df=2; *p*=1.00
66 – 82	19 (70.4)		4 (44.4)		0 (0)		6 (66.7)		1 (16.7)		11 (64.7)		7 (58.3)	
Total	27 (100)		9 (100)		5 (100)		9 (100)		6 (100)		17 (100)		12 (100)	

[I] IHD described as myocardial infarction (MI) and/or ischaemia (angina) ± heart failure (HF)

[ii] Non dilated cardiomyopathy ± heart failure but underlying aetiology not indicated

[III] Heart failure without underlying aetiology reported as primary condition for 9 men aged between 50 and 82.

[IV] Some participants experienced more than one arrhythmia

[V] Bradycardia

χ^2 = Pearson Chi-square statistic NB Some cells had an expected count <5. Fisher's exact *p* values reported

df =Degrees of freedom NB Rhythm was assessed as three (Yes, No, Don't Know) groups

p = Significant at <0.05

** = Significant

Perceived severity of symptoms was self-assessed according to the New York Heart Association (NYHA) scale which is regularly used in clinical practice. Most (43) assessed themselves as class II or III though 7 stated I, no symptoms. This reflects NICE guidelines on ICD implantation which excludes those at symptom stage IV. Mann Whitney *U* tests verified that there was no significant relationship between gender (*U*=175.5; *p*=0.85) or age (*U*=349.0; *p*=0.33) and NYHA status.

4.3.2.2 Device Type And Indication

Thirty-eight (76%) participants were recommended the device within the last 6 months and the recommendation was made by a cardiac physician (cardiologist, HF, EP or ICC) in all cases. Some participants had been initially forewarned of the potential requirement for a device prior to referral to an electrophysiologist. Twenty-three participants were offered an ICD, nineteen a CRT-D and eight a CRT-P (Figure 4.5). Responses given on the survey regarding which device had been recommended were accepted (not formally checked), but it was later evident during interviews that not all participants were entirely sure whether they had an ICD or CRT-D. The ICD and CRT-D groups were initially scrutinised independently and then amalgamated to facilitate comparison of defibrillator and pacemaker devices. There was no gender difference between device types (χ^2=0.09; df=1; *p*=1.00) but as expected the CRT-P was only offered to the older (>66) age group (χ^2=6.90; df=1; *p*=0.02) (Table 4.10).

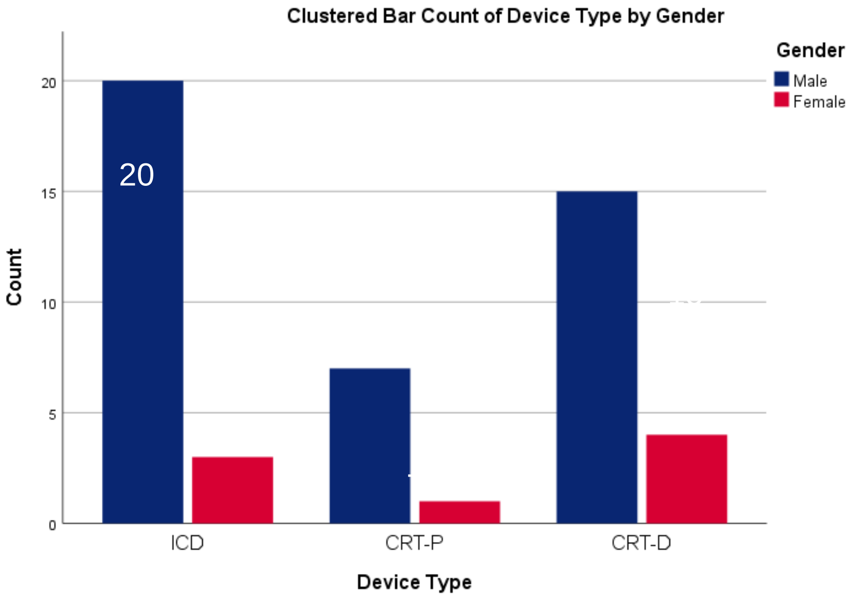


Figure 4-5 Device Type By Gender

Table 4-10 Relationship Between Device, Gender And Age

	ICD or CRT-D n (%within group)	**CRT-P** n (%within group)	Test Statistic
Gender			
Male	35 (83.3)	7 (87.5)	χ^2 =0.09; df=1; *p*=1.00
Female	7 (16.7)	1 (12.5)	
Total	42 (100)	8 (100)	
Age Category			
34 – 65	21 (50)	0 (0)	χ^2 =6.90; df=1; ***p*=0.02****
66 – 82	21 (50)	8 (100)	
Total	42 (100)	8 (100)	

χ^2 = Pearson Chi-square statistic NB Some cells had an expected count <5 Fisher's exact *p* value reported
df =Degrees of freedom
p = Significant at <0.05
**= Significant

Forty seven (94%) participants accepted the recommendation for device therapy, 2 (4%) women and one (2%) man declined. Two patients refused an ICD. One declined the CRT-D but eventually accepted the CRT-P therefore data was analysed within the decline group. Only one participant indicated on the survey that they had considered declining an ICD prior to finally accepting the device. On reflection, this would have been a useful question to pose.

4.3.3 Is there a relationship between socio-demographic characteristics and / or situational factors and self-reported coping style?

When confronted with an impending medical threat, individuals are thought to adopt monitor-blunter informational coping styles (Miller, 1987). Monitoring refers to the extent to which an individual seeks threat relevant information. High monitors actively engage in searching for threat relevant information, whereas low monitors or blunters tend to avoid such information and are more likely to employ distraction techniques. The TMSI (van Zuuren et al., 1996) was used to assess participant levels of monitoring. There is debate regarding how to use data from such scoring tools with respect to using parametric or non-parametric statistics. In the literature, monitoring scores are consistently treated as interval data (Rood et al., 2015; Muusses et al., 2012; Michel et al., 2011). Therefore, that is the approach adopted for this study. The sample mean monitoring score for this study was 34.68, SD 11.52. Table 4.11 summarises the relationship between a range of socio-demographic characteristics and monitoring scores.

Table 4-11 Relationship Between Socio-demographic Characteristics And Mean Monitoring Scores

	Mean Monitoring Mean (SD)	Test Statistics	95% CI Lower- Upper
Gender			
Male n=42	34.02 (11.80)	*t*= -0.92; df=48; *p*=0.36	-13.05 to 4.85
Female n=8	38.13 (9.89)		
Age	34.68 (11.52)	*t*=-4.63;df=48;**p=<0.001****	**-0.79 to -0.31****
Age Category			
Group 1 34-65 (21)	40 (10.67)	*t*= 2.99; df=48; **p=0.004****	**3.02 to 15.33****
Group 2 66-82 (29)	30.83 (10.7)		
Religion			
Christian (39)	34.13 (11.60)	*t*=-0.63; df=48; *p*=0.53	-10.47 to 5.45
Other / None (11)	36.64 (11.57)		
Ethnicity			
White British (49)	34.27 (11.26)	NA	NA
Other (1)	55.0		
Marital Status			
Single (4)	35 (18.78)	*F*=0.15; df=3; *p*=0.93	
Married/CP (40)	35.05 (11.48)		
Sep/Divorced (4)	32 (7.21)		
Widow/er (2)	30.5 (3.54)		
Social Support			
Lives With:-			
Next Of Kin (41)	35.05 (11.48)	*F*=0.23; df=2; *p*=0.80	
Kin Nearby (3)	30.33 (9.29)		
Friends Nearby (6)	34.33 (14.15)		
Employment Status			
Employed (15)	38.47 (10.99)	*F*=1.37; df=2; *p*=0.26	
Retired (33)	32.76 (11.73)		
Seeking or Unemployed (2)	38.00 (7.07)		

t = Independent *t* tests
F= ANOVA
df =Degrees of freedom
p = Significant at <0.05
CI= 95% Confidence interval
**= Significant
NA = Not applicable

4.3.3.1 Monitoring By Gender And Age

Mean monitoring was slightly higher in women (M=38.13; SD 9.89) than men (M=34.02; SD 11.80) though not significantly so (*t*=-0.92; df=48; *p*=0.36; CI -13.05 to 4.85). Figure 4.6 illustrates an apparent inverse relationship between age and mean monitoring.

Figure 4-6 Mean Monitoring By Age

Pearson's correlation confirmed the existence of an inverse relationship between age and monitoring scores (*r*=-0.56; n=50; *p*<0.001) (Table 4.11). Linear regression modelling revealed an unadjusted r^2=0.30 (30%) for monitoring. That is, age accounts for 30% of the difference in mean monitoring. This represents a moderate effect size between age and mean monitoring according to Cohen's classification[6]. The unstandardized *β* coefficient confirms an inverse relationship between increasing age and decreasing monitoring (*β*=-0.56; *t*=-4.63; *p*=<0.001; CI -0.79 to -0.31). The assumptions of linearity, homogeneity and homoscedasticity required to run the test were met (Gray, C. and Kinnear, 2012).

Figure 4-7 Mean Monitoring By Age And Male Gender

[6] Cohen's Classification Of Strength Of Association Tables are available in the supplementary information.

Figure 4-8 Mean Monitoring By Age And Female Gender

Thus, monitoring scores are associated with age. Despite the small number of women in the sample, the scatterplots by gender illustrate a similar pattern (Figure 4.7 and 4.8). The mean monitoring scores for the two age categories were computed to further assess the potential impact of age upon monitoring scores (Figure 4.9).

Figure 4-9 Monitoring Scores For Each Age Category

Table 4.11 displays the results for the independent samples *t* tests to compare means of age categories and monitoring scores. The *t* test confirmed a significant difference in mean monitoring between younger and older adults (*t*=2.99; df=48; *p*=0.004; CI 3.02 to 15.33). Cohen's index *d* (Cohen, 1988) was used to determine the effect size;

$$S_{\text{pooled}} = \sqrt{\frac{S_1^2 + S_1^2}{2}} \text{ and } d = \frac{M_1 - M_2}{S_{\text{pooled}}}$$

Cohen's *d* for group 1 and 2 was (40 – 30.83)⁄10.68 = 0.85. According to Cohen's classification increasing age has a large inverse effect upon mean monitoring scores[6].

4.3.3.2 Monitoring By Religion, Marital Status And Social Support

Religion, ethnicity, marital status, social support and employment status were not significantly associated with mean monitoring (Table 4.11).

4.3.3.3 Monitoring By Education, Occupation And Health Literacy

Table 4.12 summarises the monitoring scores by education, occupation and health literacy (HL).

Table 4-12 Relationship Between Educational Level, Occupational Status, Health Literacy And Mean Monitoring

	Mean Monitoring Mean (SD)	Test Statistics	95% CI Lower- Upper
Education (Years)			
Group 1 <11 Years n=24	29.54 (10.16)	*F*= 6.74; df=2; ***p*=0.003****	
Group 2 11-13Years n=15	36.87 (11.01)	Post Hoc Tukey Group 1 significantly lower score than groups 2 and 3 ***p*=0.003****	**4.23 to 22.51****
Group 3 >13 Years n=11	42.91 (9.92)		
Occupational Status			
Unskilled Manual n=8	31.25 (13.81)	*F*= 3.58; df=4; ***p*=0.01****	
Semi Skill Man n=12	27.33 (8.23)	Post Hoc Tukey Semi skilled significantly lower score than professional ***p*=0.008****	**3.51 to 31.82****
Clerical n=4	36.50 (3.87)		
Managerial n=19	36.58 (10.72)		
Professional n=7	45.00 (11.12)		
Estimated Health Literacy			
Lower Aptitude n=21	29.33 (10.57)	*t*=3.01; df=48 ***p*=0.004****	**3.07 to 15.37 ****
Higher Aptitude n=29	38.55 (10.75)		

t = Independent *t* tests
F= ANOVA
df =Degrees of freedom
p = Significant at <0.05 CI= 95% Confidence interval **= Significant

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[6] Cohen's Classification Of Strength Of Association Tables are available in the supplementary information.

Table 4.12 presents the relationship between educational years, occupational status, aptitude for HL and monitoring scores. ANOVA confirmed a significant difference in monitoring scores and years in formal education (*F*=6.74; df=2; *p*=0.003; CI 4.23 to 22.51). Post hoc Tukey tests confirmed that the significant difference occurred between those who were educated for less than 11 years (group 1) and more than 11 years (group 2 and 3) (*p*=0.003). An association was also apparent between occupation and monitoring (*F*=3.58; df=4; *p*=0.01; CI 3.51 to 31.82). Post hoc Tukey tests confirmed the difference in monitoring to be between the semi-skilled and professional groups (*p*=0.008). The combination of occupational and educational status to inform the crude estimation of aptitude for HL was corroborated by a significant association between estimated HL and monitoring (*t*=3.01; df=48; *p*=0.004; CI 3.07 to 15.37). Increasing age and lower level HL were significantly associated with lower level monitoring, yet there did not appear to be a significant relationship between age and HL (*r*=-0.23; *p*=0.10).

4.3.3.4 Monitoring And Cardiac Condition, Symptom Severity And Device Type

Table 4.13 summarises the statistical findings related to cardiac condition, symptoms severity and device type. There was an association between cardiac condition and monitoring (*f*=3.84; df=3; *p*=0.02). Post hoc tests specifically identified a difference between those with known IHD and HCM (*p*=0.04; CI 27.57 to 0.04) with significantly higher monitoring scores among the latter group. This may be attributed to the difference in mean age of each group. Twenty participants were either unaware of or denied rhythm abnormalities. ANOVA tests found that the presence or not of tachycardia and bradycardia and symptom severity according to NYHA class did not significantly affect mean monitoring (Table 4.13).

To assess whether the defibrillator component had any effect, the device categories were re-grouped in to ICD and CRT-D (n = 42) and CRT-P (n = 8). Although CRT-P recipients were in the older age group, independent samples *t* tests did not reveal a significant difference in levels of monitoring between the device groups (Table 4.13).

Table 4-13 Relationship Between Cardiac Condition, NYHA, Device Type And Mean Monitoring

	Mean Monitoring Mean (SD)	Test Statistics	95% CI Lower- Upper
Cardiac Condition			
Known IHD n=27	31.04 (10.84)		
NIDCM n=9	41.44 (13.44)	*F*= 3.84; df=3; ***p*=0.02****	0.04 to 27.57
HCM / ARVC n=5	44.80 (7.46)		
HF only n=9	33.22 (7.78)		
VT / VF n=6	40.00 (12.59)		
SVT n = 16	34.00 (12.31)		
Bradycardia n=8	40.88 (8.90)	*F*= 1.47; df=4; *p*=0.23	
None n=10	32.10 (11.41)		
Don’t Know n=10	30.20 (10.34)		
NYHA			
I n=7	43.57 (8.56)		
II n=17	31.41 (11.46)	*F*= 3.0; df=2; *p*=0.06	
III n=26	34.42 (11.36)		
Device Type			
ICD / CRT-D n=42	36.0 (11.56)		
CRT-P n=8	27.75 (6.36)	*t*= 1.90; df=48; *p*=0.06	-0.46 to 16.96

t = Independent *t* tests
F= ANOVA
df =Degrees of freedom
p = Significant at <0.05
CI= 95% Confidence interval
**= Significant

Multiple linear regression was performed to investigate the extent to which gender, age, HL and cardiac condition was associated with monitoring scores (Table 4.14). Use of HL as a composite measure of educational and occupational status eliminated the risk of multicollinearity between the latter variables. Collinearity diagnostics confirmed no multicollinearity and the distribution of the scatter plot residuals revealed no homoscedasticity. The combination of occupational and educational status to inform the crude estimation of aptitude for HL was corroborated by a significant association between estimated HL and monitoring (β=9.22; *t*=3.01; *p*=0.004; CI 3.07 to 15.37; adjusted r^2= 0.14; 14%) (Table 4.14). When adjusted for gender, age, HL and cardiac condition, the results of the regression indicated that the model explained r^2=.35 (35%) of the variance. Only age (β=-0.48; *t*=-4.04; *p*=<0.001; CI -0.72 to -0.24) and HL (β=7.03; *t*=2.49; *p*=0.02; CI 1.35 to 12.72) contributed to the predictive model but gender and cardiac condition did not.

The odds ratio (*OR*) was computed to assess the association between aptitude for health literacy (HL) and monitoring scores. Those with low aptitude for HL scores were significantly more likely to have a low monitoring score than those with a high HL (71% versus 41% respectively, *OR*=3.54; 95% CI 1.07 to 11.77).

Table 4-14 Summary Of Linear Regression Analysis For Variables Predicting Monitoring Scores

Independent Predictor Variables		**Unadjusted**				**Adjusted**			
Model Constant	Monitoring	Adjusted r^2	Regression Coefficient	*p* level	CI (95%) Lower- Upper	Adjusted r^2	Regression Coefficient	*p* level	CI (95%) Lower- Upper
1	Gender	-0.003	β= 4.10; t=0.92	0.36	-4.85 to 13.05	-0.003	β= 4.10; t= 0.92	0.36	-4.85 to 13.05
2	Gender						β= 0.74; t= 0.19	0.85	-6.99 to 8.47
	Age	0.30(30%)	β= -0.55; t=-4.63	**<0.001****	**-0.79 to -0.31****	0.28(28%)	β= -0.54; t= -4.46	**<0.001****	**-0.79 to -0.30****
3	Gender						β= 1.82; t= 0.50	0.62	-5.49 to 9.13
	Age						β= -0.48; t= -4.12	**<0.001****	**-0.72 to -0.25****
	Health Literacy (HL)	0.14(14%)	β= 9.22; t=3.01	**0.004****	**3.07 to 15.37****	0.37(37%)	β= 7.27; t= 2.70	**0.01****	**1.85 to 12.69****
4	Gender						β= 1.83; t= 0.50	0.62	-5.56 to 9.23
	Age						β= -0.48; t= -4.04	**<0.001****	**-0.72 to -0.24****
	Health Literacy (HL)						β= 7.03; t= 2.49	**0.02****	**1.35 to 12.72****
	Cardiac Condition	0.01 (1%)	β= 1.81; t=1.30	0.20	-0.98 to 4.61	0.35(35%)	β= 0.36; t= 0.31	0.76	-2.02 to 2.74

β = Unstandardised beta coefficient
t = t tests
df =Degrees of freedom
p = Significant at <0.05
CI= 95% Confidence interval
**= Significant

4.3.4 Do demographic, situational and coping style factors influence the patients approach to decision making?

The decision approach was judged by the level of engagement with, source and type of additional information seeking pursued. Most participants gleaned information from more than one source (Figure 4.10). Eight (16%) stated that they did not require any further information, accepting the information received at recommendation only.

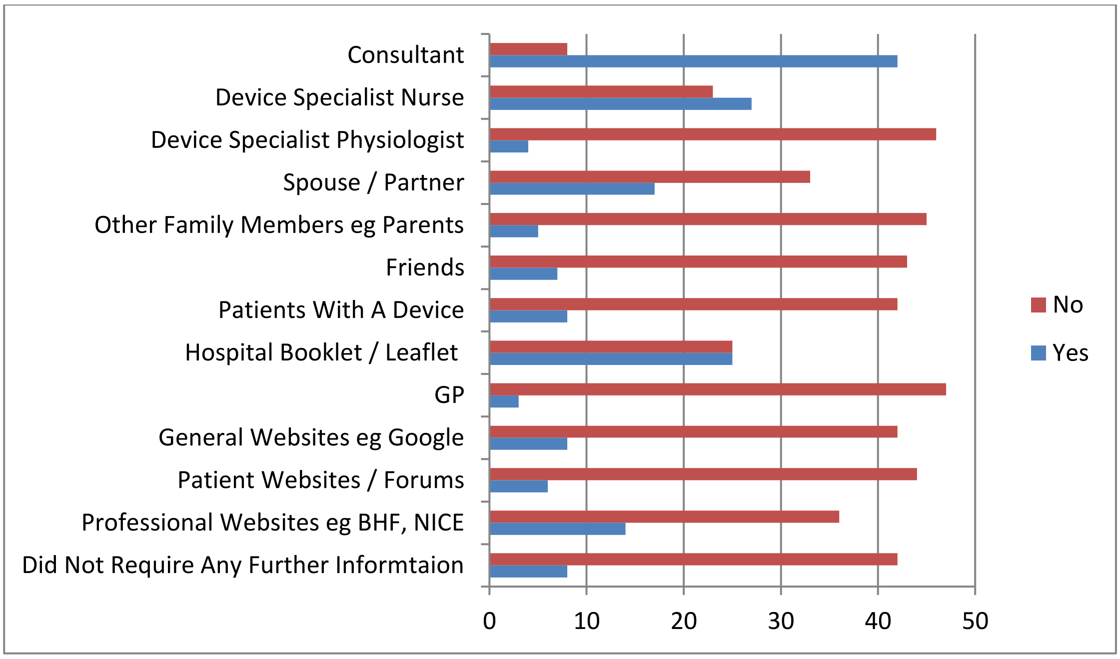
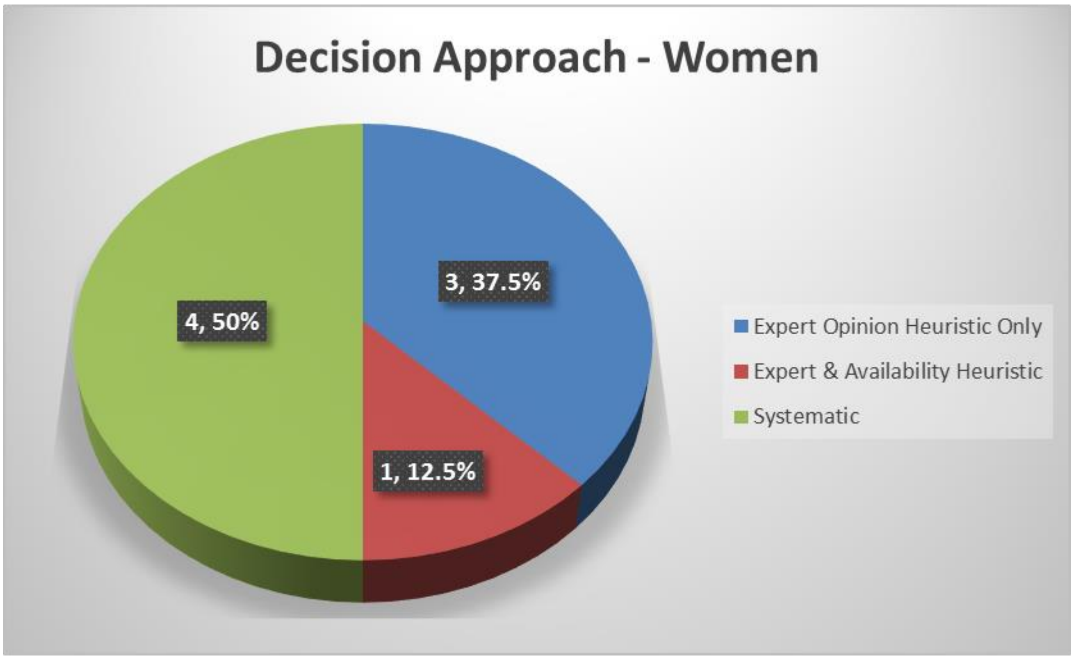


Figure 4-10 Source Of Information Received

Based upon responses to Q26 and type of information sought, eighteen (15 men, 3 women) were described as ‘expert opinion’ heuristic information gatherers and seventeen (16 men, 1 woman) ‘expert and availability’ heuristic information gatherers. For analytical purposes, they were grouped together as ‘heuristic’ information gatherers (n=35). Fifteen (11 men, 4 women) were described as active, ‘systematic’ information gatherers (Figure 4.11). Almost the same proportion of men and women accepted expert opinion alone. A higher proportion of men (38%) referred to expert and availability opinion than women (12.5%). Whereas, half the women compared with 26% of men adopted a systematic approach. In this study, the women (n=8) did not refer specifically to their partner for information or advice revealing a significant gender difference ($\chi^2 = 4.91$; df=1; $p=0.04$).



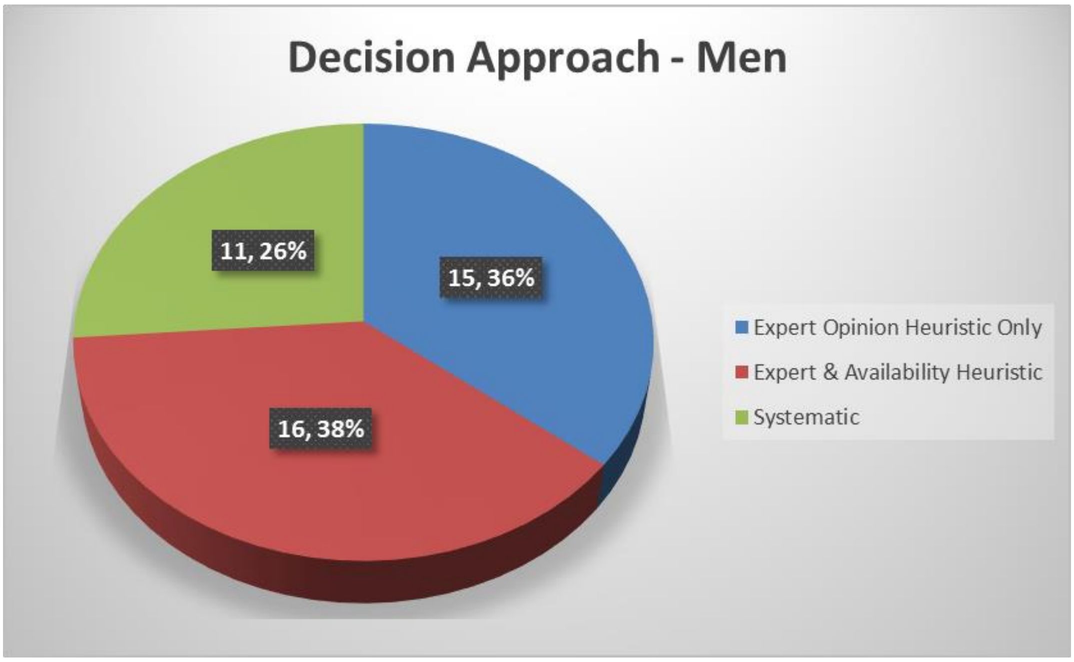


Figure 4-11 Decision Approach By Gender

Gender, religion, ethnicity, marital status and social support were not significantly associated with the decision approach (Table 4.15). Age, educational and occupational status, HL, cardiac condition and monitoring score were significant factors in determining information seeking behaviour (Table 4.15). The mean age of participants who engaged with heuristic information gathering (M=70.40; SD 9.26) was significantly higher than the mean (M=57.20; SD 11.75) for those who systematically gathered information (χ^2=8.64; df=1; *p*=0.005). Odds ratio also revealed a greater propensity to adopt heuristic decision making among the older group (86% versus 48%; OR 0.15; 95% CI 0.04 to 0.57) than the younger group.

Table 4-15 Relationship Between Socio-demographic Variables And Decision Approach

	Heuristic Information Gatherers % Within Group	**Systematic Information Gatherers** % Within Group	Test statistic df; *p* level
Gender			χ^2 =1.81; df=1; *p*=0.22
Male n=42	31 (88.6)	11 (73.3)	
Female n=8	4 (11.4)	4 (26.7)	
Age Category			χ^2 =8.64; df=1; ***p*=0.005****
34 – 65	10 (28.6)	11 (73.3)	
66 – 82	25 (71.4)	4 (26.7)	
Religion			χ^2 =5.13; df=2; *p*=0.07
Christian	30 (85.7)	9 (60)	
Other	0	1 (6.7)	
None	5 (14.3)	5 (33.3)	
Ethnicity			χ^2 =3.38; df=1; *p*=0.30
White British	35 (100)	14 (93.3)	
Other	0	1 (6.7)	
Marital Status			χ^2 =2.84; df=3; *p*=0.44
Single	3 (8.6)	1 (6.7)	
Married / CP	29 (82.9)	12 (80)	
Separate/Divorce	1 (2.9)	2 (13.3)	
Widow/er	2 (5.7)	0	
Social Support			χ^2 =0.06; df=2; *p*=1.00
With Next Of Kin	29 (82.9)	12 (80)	
Next of Kin Nearby	2 (5.7)	1 (6.7)	
Live Alone, Friends	4 (11.4)	2 (13.3)	
Education (Years)			χ^2 =7.37; df=2; ***p*=0.02****
<11 Years	21 (60)	3 (20)	
11 to 13 Years	9 (25.7)	6 (40)	
> 13 Years	5 (14.3)	6 (40)	
Occupational Status			χ^2 =18.74; df=4; ***p*=0.001****
Unskilled Manual	9 (25.7)	1 (6.7)	
Semi-skill Manual	9 (25.7)	1 (6.7)	
Clerical	1 (2.9)	3 (20)	
Managerial	15 (42.9)	4 (26.7)	
Professional	1 (2.0)	6 (40)	
Estimated Health Literacy			χ^2 =4.26; df=1; *p*=0.06
Lower Aptitude	18 (51.4)	3 (20)	
Higher Aptitude	17 (48.6)	12 (80)	

χ^2 = Pearson Chi-square statistic NB Some cells had an expected count <5. Fishers exact *p* value reported
df =Degrees of freedom
p = Significant at <0.05
**= Significant

Table 4.15 show that participants with a lower education level (χ^2= 7.37; df=2; *p*=0.02) and the unskilled and semi-skilled occupational groups (χ^2=18.74; df=4; *p*=0.001) were more likely to engage in heuristic decision making. Although Pearson's Chi-square corroborated an association between estimated aptitude for HL and decisional approach (χ^2=4.26; df=1; *p*=0.04), the Fisher's exact *p*=0.06 did not support the level of significance. On closer inspection, there was no difference in the proportion who scored high and low on the HL estimation among the heuristic decision makers. Whereas, the systematic decision makers were more likely to be categorised within the higher HL group (Figure 4.12). The odds of the higher aptitude HL group adopting a systematic approach was 4 times higher than those with a lower aptitude HL (80% versus 20%; OR 4.24; 95% CI 1.02 to 17.67).

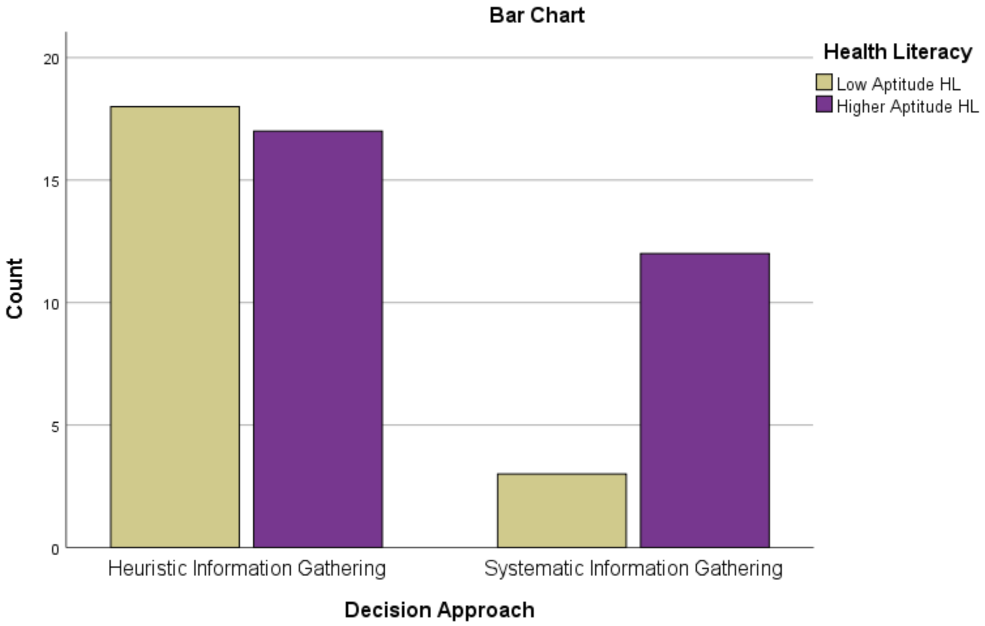


Figure 4-12 Decision Approach By Estimated Health Literacy

A relationship between a diagnosis of known IHD and heuristic information gathering (χ^2=9.97; df=1; *p*=0.002) was probably linked to the advancing age of the known IHD group (Table 4.16). Significantly, all five younger participants with HCM or ARVC were systematic information gatherers (χ^2=12.96; df=1; *p*=0.001). Participants who reported a VT/VF rhythm were also more likely to adopt a systematic approach (χ^2=6.55; df=2; *p*=0.04). Other conditions including NIDCM, bradycardia and SVT did not appear to have any influence upon decision approach. NYHA classification as a measure of symptom severity (χ^2=3.70; df=2; *p*=0.19), the decision to accept or decline (χ^2=2.04; df=1; *p*=0.15) and device type (χ^2=1.39; df=1; *p*=0.41) were not significantly related to information seeking.

To facilitate further analysis of a potential association between monitoring and decision approach, monitoring scores were transformed into dichotomous groups. Scores below and above the mean (M=34) were categorised as low and high monitors respectively. The assumption that heuristic information processing would be associated with low monitoring was verified (χ^2=14.27; df=1; *p*=<0.001). The odds of people with low monitoring characteristics adopting a heuristic decision approach was 16.25 times higher than if they displayed high monitoring (93% versus 7%; OR 16.25; 95% CI 3.09 to 85.42).

Table 4-16 Relationship Between Cardiac Condition, Device, Monitoring And Decision Approach

	Heuristic Information Gatherers % Within Group	**Systematic Information Gatherers** % Within Group	Test statistic df; *p* level
Cardiac Condition			
Known IHD			
Yes	24 (68.6)	3 (20)	χ^2 =9.97; df=1; ***p*=0.002****
No	11 (31.4)	12 (80)	
NIDCM			
Yes	4 (11.5)	5 (33.3)	χ^2=3.41; df=1; *p*=0.11
No	31 (88.5)	10 (66.7)	
HCM / ARVC			
Yes	0	5 (33.3)	χ^2=12.96; df=1; ***p*=0.001****
No	35 (100)	10 (66.7)	
VT / VF			
Yes	2 (5.7)	4 (26.7)	χ^2 =6.55; df=2; ***p*=0.04****
No	22 (62.9)	10 (66.7)	
Don't Know	11 (31.4)	1 (3.6)	
SVT			
Yes	11(31.4)	6 (40)	
No	12 (34.3)	8 (53.3)	χ^2=4.26; df=2; *p*=0.13
Don't Know	12 (34.3)	1 (6.7)	
Bradycardia			
Yes	7 (20)	5 (33.3)	χ^2 =1.12; df=2; *p*=0.61
No	18 (51.4)	7 (46.7)	
Don't Know	10 (28.6)	3 (20)	
NYHA			
I n=7	3 (8.6)	4 (26.7)	
II n=17	14 (40)	3 (20)	χ^2 =3.70; df=2; *p*=0.19
III n=26	18 (51.4)	8 (53.3)	
Device Type			
ICD / CRT-D n=42	28 (80)	14 (93.3)	χ^2=1.39; df=1; *p*=0.41
CRT-P n=8	7 (20)	1 (6.7)	
Monitoring Score	M=30.69; SD 10.50	M=44.00; SD 7.98	χ^2=14.27; df=1; ***p*=<0.001****

χ^2 = Pearson Chi-square statistic NB Some cells had an expected count <5. Fishers exact *p* value reported
df =Degrees of freedom
p = Significant at <0.05
CI= 95% Confidence interval
**= Significant

Likewise, the odds of high monitors adopting a systematic approach was greater than if they had been low monitors (87% versus 13%; OR 16.25; 98% CI 3.09 to 85.42).

Binary logistic regression was performed to predict the dichotomous categorical dependent variable (decision approach), from a range of continuous and qualitative covariates (gender, age, estimated HL and monitoring score) (Table 4.17). The iteration history confirmed convergence of estimates with each additional covariant to three decimal places. The regression model improved significantly upon chance in predicting category membership (χ^2=7.17; df=1; p=<0.007). The Nagelkerke R^2 (0.51), like the coefficient of determination R^2 in multiple regression, indicated that the model contributed well to the prediction of likelihood of a heuristic decision approach (Gray, C. and Kinnear, 2012). The high value of p=0.94 of the Hosmer-Lemeshow test also confirmed that all potential systematic variance had been accounted for by the model (Gray, C. and Kinnear, 2012). When all the variables were entered, monitoring appeared to be the only significant contributor, having the highest Wald statistic (tests the unique contribution of each predictor) (β=2.17; Wald=3.70; df=1; p=0.02; ExpB=1.09; 95% CI for ExpB 1.00 to 1.19).

Table 4-17 Summary Of Logistic Regression Analysis For Variables Predicting Decision Approach

Covariates	**Unadjusted**					**Adjusted**				
Model	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2
Gender	-1.04 (0.79)	1.72	0.19	0.08 to 1.67	0.05	-1.01 (1.04)	0.94	0.33	0.05 to 2.81	0.05
Age (years)	-0.12 (0.04)	10.10	**0.001****	**0.83 to 0.96****	0.36	-0.08 (0.04)	3.46	0.06	0.85 to 1.00	0.37
Health Literacy	1.44 (0.73)	3.92	**0.05****	**1.02 to 17.67****	0.12	0.99 (0.89)	1.22	0.27	0.47 to 15.40	0.43
Monitoring score	0.13 (0.04)	10.79	**0.001****	**1.05 to 1.22****	0.38	0.09 (0.05)	3.70	**0.02****	**1.00 to 1.19**	0.51

B regression coefficient

SE=Standard Error

p = Significant at <0.05

CI= 95% Confidence interval for ExpB

**= Significant

4.3.5 What effect does demographic difference, situational context, coping style and decision approach have upon acceptance and refusal of CRMD therapy?

The full range of potential influences upon the decision studied can be found in Tables 4.18 and 4.19. Gender was not associated with the decision to accept or refuse, though this may have been related to the small sample and could represent a type II error, where an inability to detect a difference was due to the small sample size (Gray, J. et al., 2017).

Table 4-18 Influences Upon The Decision to Accept Or Refuse A Device

Group	**Factor**	**Accepted Device (n)**	**Refused Device (n)**	**Pearson's X^2** (Unless stated)	**Fishers Exact Sig. (2-sided)**
Gender	Male Female	41 6	1 2	6.10 (df=1)	*p*=0.06
Age*		M=67.36 (SD 10.89)	M=52 (SD 16.70)	*t*=2.31; df=48; CI 1.96 to 28.76	***p*=0.03****
Age Category	34 – 49 50 – 69 70 - 82	4 15 24	1 2 0	3.73 (df=2)	*p*=0.08
Religion	Christian Other None	37 0 10	2 1 0	16.36 (df=2)	*p*=0.07
Ethnicity	White British Other	47 0	2 1	15.97 (df=1)	*P*=0.06
Marital Status	Single Married / CP Separate/Divorce Widow/er	3 39 3 2	1 2 0 0	2.97 (df=3)	*p*=0.46
Social Support	With Next Of Kin Next of Kin Nearby Live Alone, Friends	39 3 5	2 0 1	1.49 (df=2)	*p*=0.46
Education	<11 years 11 – 13 years >13 years	23 15 9	1 0 2	3.99 (df=2)	*p*=0.20
Occupation	Unskilled Manual Semi-Skilled Clerical Managerial Professional	9 10 4 18 6	1 0 0 1 1	2.05 (df=4)	*p*=0.73
Health Literacy	Low Average Above Average	20 17 10	1 0 2	3.56 (df=2)	*p*=0.24

NB Some cells within each factor have expected count less than 5 therefore Fishers exact *P* value reported
* Mean, Standard Deviation, Independent *t* tests and Confidence Intervals given
** Statistically significant

Age and a diagnosis of HCM / ARVC was associated with an increased prospect of refusal (χ^2=11.43; df=2; *p*=0.04), which reflects the younger group. Understandably a history of VT or VF was also significantly associated with acceptance (χ^2=10.11; df=2;

p=0.01). Despite being small in number, mean monitoring scores were significantly higher among those who refused a device (M=50.67 versus M=33.66; *t*=-2.62; df=48; *p*=0.01; CI -30.04 to -3.97).

Table 4-19 Influences Upon The Decision to Accept Or Refuse A Device

Group	**Factor**	**Accepted Device (n)**	**Refused Device (n)**	**Pearson's X^2** (Unless stated)	**Fishers Exact Sig. (2-sided)**
Cardiac Condition	Known IHD	26	1	0.84 (df=2)	*p*=0.62
	NIDCM	9	0	1.12 (df=2)	*p*=1.00
	HCM / ARVC	3	2	11.43 (df=2)	**_p_=0.04****
	VT or VF	4	2	10.11 (df=2)	**_p_=0.01****
	SVT	16	1	0.10 (df=2)	*p*=1.00
	Bradycardia	10	2	4.08 (df=2)	*p*=0.07
NYHA	I	6	1	3.51 (df=2)	*p*=0.13
	II	15	2		
	III	26	0		
Device Type	ICD	21	2	0.83 (df=2)	*p*=1.00
	CRT-P	8	0		
	CRT-D	18	1		
Mean Monitoring*		M=33.66 (SD 11)	M=50.67 (SD 3.79)	*t*=-2.62; df=48; CI-30.04 to -3.97	**_p_=0.01****
Decision Approach	Systematic	13	2	2.04 (df=1)	*p*=0.21
	Heuristic	34	1		
Device Aware	Yes	21	2	0.55 (df=1)	*p*=0.59
	No	26	1		
Knowledge Recall	Accept B & R	44	3	0.20 (df=1)	*p*=1.00
	Refuse B & R	27	3	2.13 (df=1)	*p*=0.27
	Alternatives	21	3	3.46 (df=1)	*p*=0.10
	Physical Issues	34	2	0.05 (df=1)	*p*=1.00
	Emotional	20	2	0.67 (df=1)	*p*=0.58
	Social Activity	32	3	1.37 (df=1)	*p*=0.55
	Work & Home	21	3	3.46 (df=1)	*p*=0.10
	No Discussion	2	0	0.13 (df=1)	*p*=1.00
Levels Of Recall	High (>4 elements)	25	3	2.51 (df=1)	*p*=0.25
	Low (<3 elements)	22	0		

NB Some cells within each factor have expected count less than 5 therefore Fishers exact *P* value reported
* Mean, Standard Deviation, Independent *t* tests and Confidence Intervals given
** Statistically significant

The decision was not significantly influenced by any other socio-demographic and situational factors, decision approach or levels of information recall.

Logistic regression was performed to investigate whether age, monitoring score, decision approach and levels of knowledge recall could significantly predict the decision. The results indicated that the monitoring score alone (β=-0.17; Wald=3.77; df=1; *p*=0.03; ExpB 0.84; 95% CI for ExpB 0.71 to 1.00) marginally contributed to the final predictive model.

4.3.6 What effect does demographic difference, situational context, coping style, decision approach and acceptance or refusal of therapy have upon decisional regret?

Participants were categorised into regret and no regret groups. 50% of the participants did not report decisional regret and the overall mean for those that did was low (M=12.5; SD 23.13). As reports of regret were minimal, statistical analysis failed to detect any significant association between any variables and decisional regret.

4.3.7 Is there an association between the degree of match between desired and actual decision control, the final decision and decisional regret?

The treatment decision making literature frequently refers to the impact of the patients perceived level of decisional control upon outcomes. Cancer treatment decision studies have concluded that achieving the preferred amount of involvement in decision making was associated with greater satisfaction, reduced anxiety, less depression (Vogel et al., 2009), and improved health related quality of life (HRQOL) regardless of the treatment choice (Anderson et al., 2009). Conversely a mismatch between desired and actual participation has been associated with lower satisfaction, difficulties in decision making, decisional regret (Hack, T.F. et al., 2006) and poorer patient outcomes (Kiesler and Auerbach, 2006; Gaston and Mitchell, 2005).

4.3.7.1 Decisional Control Preference (DCP)

Participants were asked to indicate their preferred (Figure 4.13) and actual (Figure 4.14) level of participation to determine whether preference could be predicted and to assess the degree of match.

A total of thirty (60%) indicated a preference for taking active control over the decision, of which seventeen acknowledged serious consideration of the experts opinion. Sixteen (32%) preferred a passive role though six (12%) of these indicated that they wanted their opinion to be seriously considered. Four (8%) desired a collaborative approach. 39 (78%) believed that they had actively made the decision either independently (16%) or having seriously considered the experts opinion (62%). Two (4%) believed it had been a collaborative decision. 9 (18%) had adopted a passive role purely based upon expert opinion (6%) or with consideration of their wishes (12%).

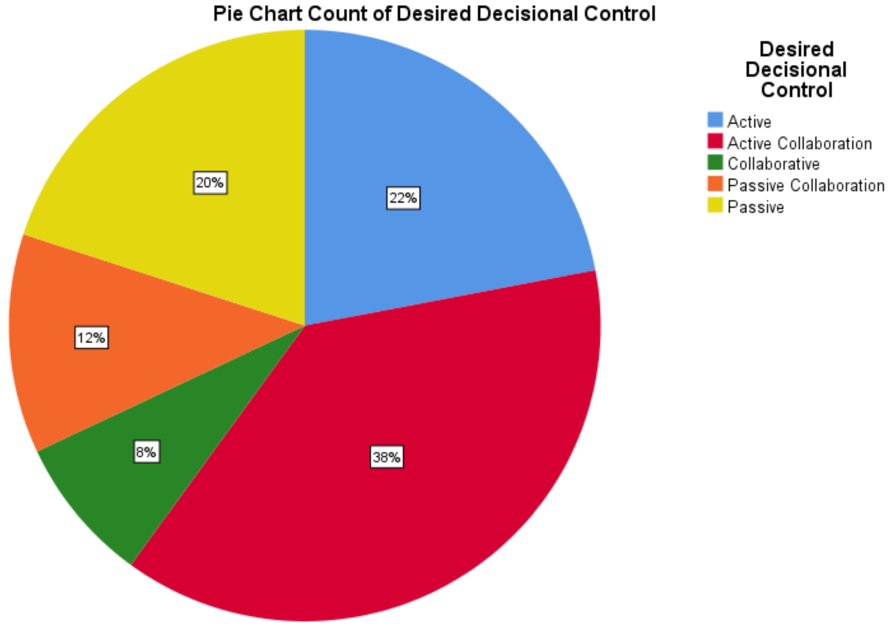


Figure 4-13 Desired Decisional Control

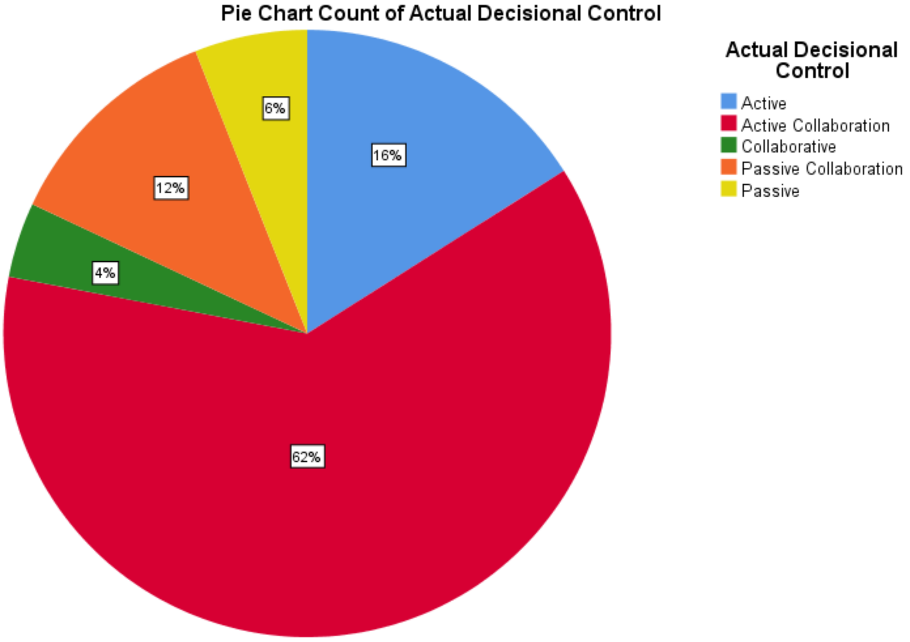


Figure 4-14 Actual Decisional Control

Table 4.20 shows the desired and actual decisional control by gender. Being male was associated with a greater desire for active control (χ^2=11.32; df=4; *p*=0.03), but gender was not associated with actual control (χ^2=2.37; df=4; *p*=0.69).

Table 4-20 Desired And Actual Decisional Control

	Male n (%)		**Female n (%)**	
	Desired	Actual	Desired	Actual
Active	10 (23.8)	7 (16.7)	1 (12.5)	1 (12.5)
Active Collaborative	17 (40.5)	26 (61.9)	2 (25)	5 (62.5)
Collaborative	2 (4.8)	1 (2.4)	2 (25)	1 (12.5)
Passive Collaborative	3 (7.1)	5 (11.9)	3 (37.5)	1 (12.5)
Passive	10 (23.8)	3 (7.1)	0	0
Total	42 (100)	42 (100)	8 (100)	8 (100)

Figure 4.15 depicts the desired and 4.16 the actual decisional control by age group. Age category was not a significant factor for desired (χ^2=7.59; df=4; *p*=0.12), whereas the younger group were more likely to report actual active engagement than the older group (χ^2=13.48; df=4; *p*=0.003).

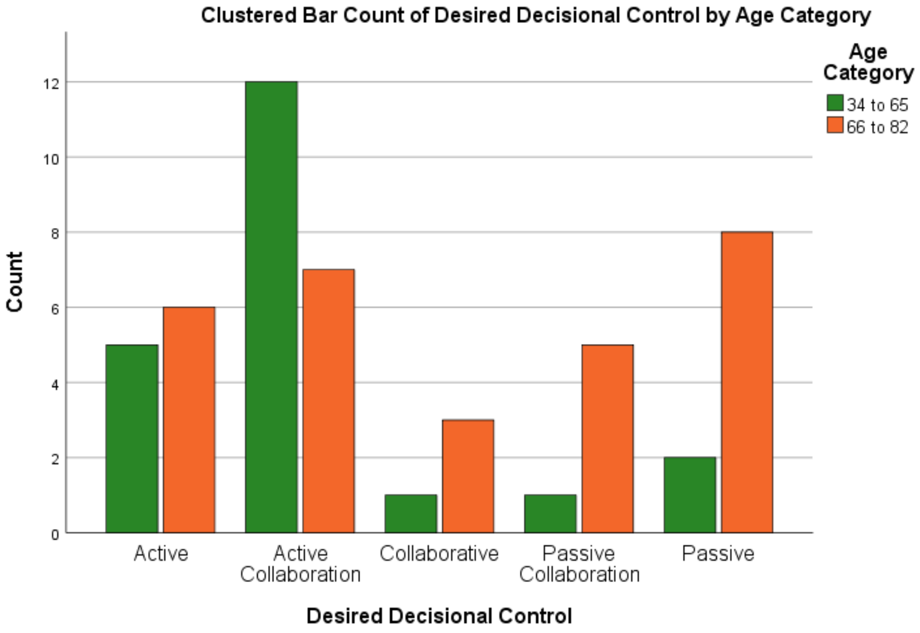


Figure 4-15 Desired Decisional Control By Age Group

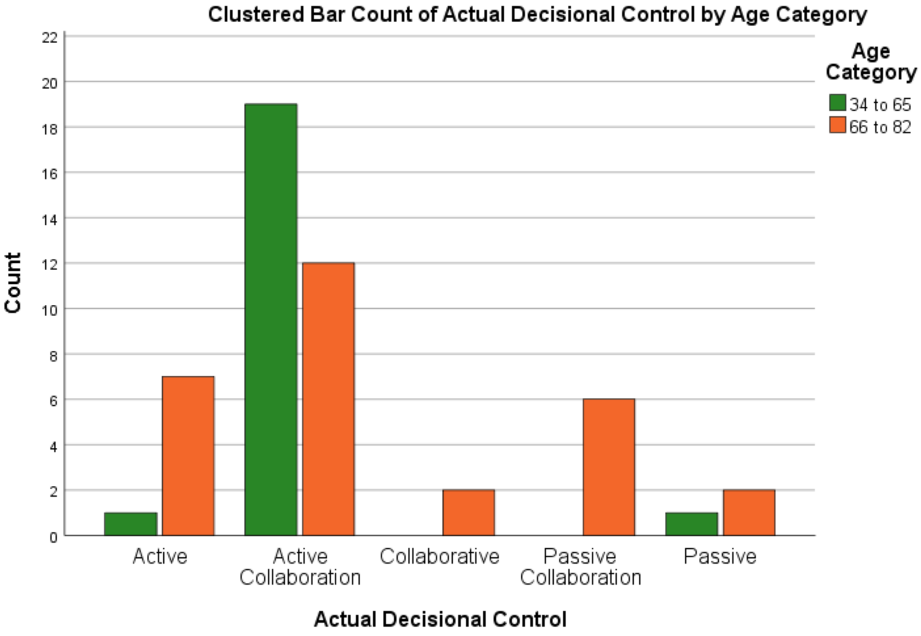


Figure 4-16 Actual Decisional Control By Age Group

Linear regression modelling revealed a slight correlation (*r*=-0.29; *p*=0.02) between lower monitoring scores and a preference for passive decision making. The adjusted r^2=0.06 (6%) confirmed a small effect size according to Cohen's classification[6]. The unstandardized coefficient confirms a weak relationship between lower monitoring scores and a propensity towards passive decision making (*β*=-2.30; *t*=-2.11; *p*=0.04; CI -4.49 to -0.010). The same was not found for actual decision making. Desired and actual decisional control preferences were not associated with any other socio-demographic or situational factors, decision approach, information recall, device acceptance or regret.

4.3.7.2 Match Between Desired And Actual Decisional Control

The Degner et al. (1997b) formula, 'actual role minus preferred role = 0 (no discrepancy) to 4 (steps of discrepancy) was used to calculate a similarity score between preferred and actual decisional control. The greatest discrepancy would be if a participant wanted the most active role (A) but actually played the most passive role (E) and vice versa. Thirty one (62%) exhibited a complete match and one (2%) reported a total mismatch between preferred and actual decisional control. Eleven (22%) displayed a slight mismatch; two (4%) some mismatch and 5 (10%) significant mismatch. There was no relationship between gender (χ^2=0.58; df=1; *p*=0.46) or age category (χ^2=0.34; df=1; *p*=0.77) and control match (Figure 4.17 and 4.18).

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[6] Cohen's Classification Of Strength Of Association Tables are available in the supplementary information.

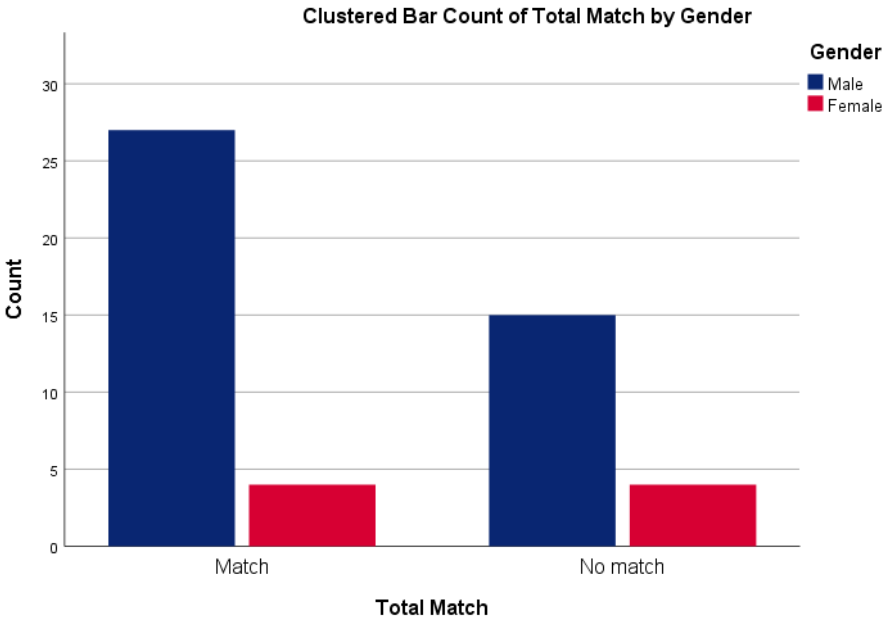

Figure 4-17 Decisional Control Match By Gender

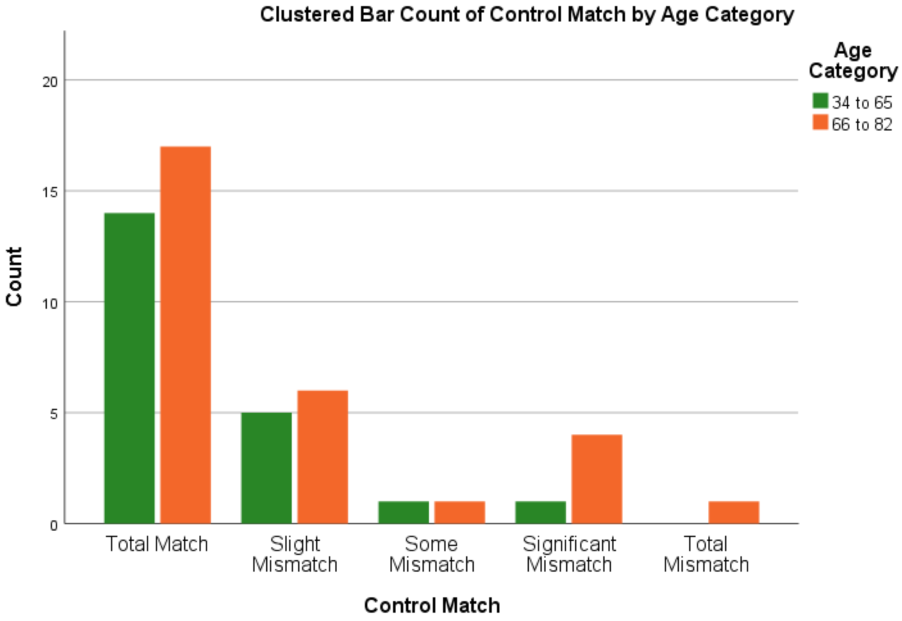

Figure 4-18 Decisional Control Match By Age Group

Decisional control match was not associated with any other socio-demographic or situational factors, monitoring or decision approach, information recall, device acceptance or regret.

4.3.8 Is there an association between individual characteristics, coping style, approach to decision making and level of knowledge acquisition and recall?

4.3.8.1 The Device Awareness

Participants were asked to indicate what and why they had a device. Twenty (40%) identified the correct reason for the device recommendation. The ICD corresponded with ‘treat rhythm’ (n=9), CRT-P to ‘treat HF’ symptoms (n=3) and the CRT-D was for both indications (n=8) (Table 4.21).

Table 4-21 Reason For Device Recommendation

Device Type	**Recommended For**	**Correct Identification**		**Incorrect Or Don’t Know**		**Total**
		Male	Female	Male	Female	
ICD	Treat Rhythm	7	2	13	1	23
CRT-P	Treat HF	3	0	4	1	8
CRT-D	Treat Rhythm & HF	6	2	9	2	19
Total		16 (38%)	4 (50%)	26 (62%)	4 (50%)	50 (100%)

Twenty six (52%) gave an incorrect reason and four (8%) did not know why the device had been recommended. The number of men who did not know the reason for an ICD (n=13) seemed disproportionate to the number who did (n=7). When a proportionality Z test was performed to determine whether the proportions were the same, the resulting Z score was 1.36. As this was lower than the pre-set Z score of 1.96 the null hypothesis of no significant difference was retained.

Four men and one woman stated incorrectly that the ICD was recommended for HF. This may be attributed to the potential to treat heart failure symptoms associated with drug induced bradycardia by ICD pacing or it may suggest recipient misunderstanding of device role or the survey question. Similarly two believed that the CRT-P was implanted to treat rhythm and heart failure though this may also have referred to bradycardia pacing. The focus upon HF treatment only by seven men and one woman receiving the CRT-D may be connected to a preponderance upon symptom severity, rather than the uncertainty of rhythm issues. The other two focused solely upon rhythm treatment. Gender (χ^2=0.06; df=1; *p*=1.00); age (*t*=-0.03; df=48; *p*=0.98; CI-6.82 to 6.64); HL (χ^2=0.98; df=2; *p*=0.67), monitoring scores (*t*=-0.90; df=48; *p*=0.37; CI-9.54 to 3.64) and decision approach (χ^2=0.004; df=1; *p*=1.00) were not associated with device awareness.

4.3.8.2 Device Information Recall

4.3.8.2.1 Alternative Treatment Options

In response to Q17, alternative treatment options had been discussed with 24 (48%) participants. Socio-demographic and situational factors, monitoring score and decision approach did not appear to influence answers to Q17.

4.3.8.2.2 Level Of Information Recall

Q18 asked participants to recall what information they had received (not the level of understanding) (Figure 4.19). They were grouped according to the number of elements recalled between none and 6, and categorised as low recall ($\leq$3 elements) and high recall ($\geq$4 elements).

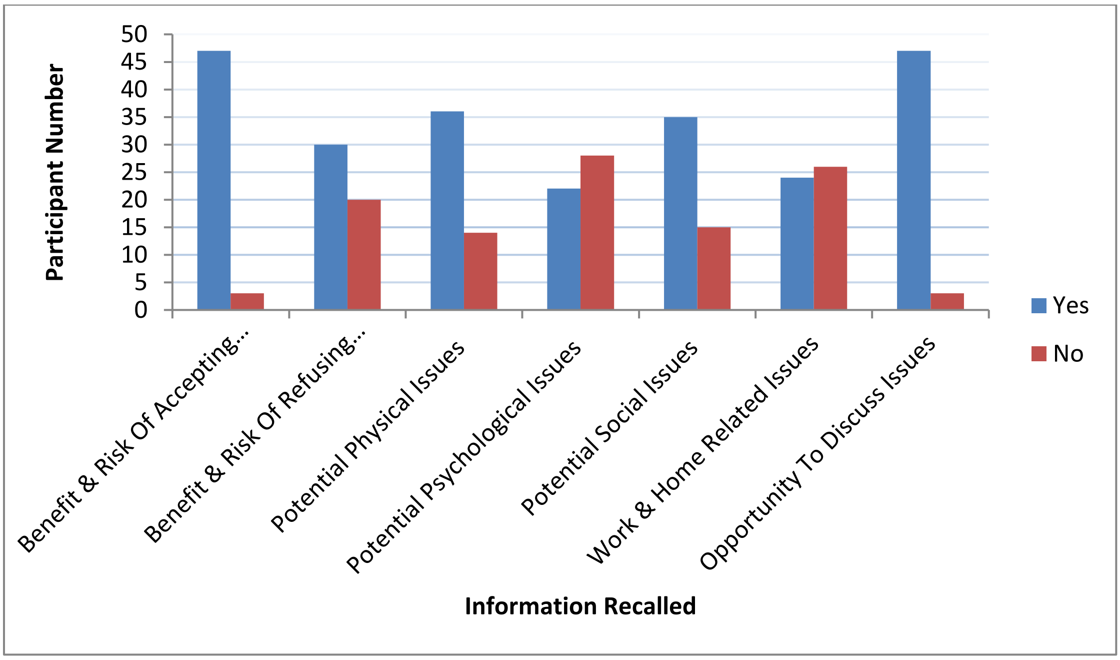

Figure 4-19 Information Recall

Binary logistic regression was undertaken to determine whether there was any association between a range of socio-demographic and situational characteristics and level of information recall (Table 4.22).

Chi-square tests suggest a relationship between device type and level of information recall (χ^2=7.31; df=1; *p*=0.02). As CRT-P were only implanted among older participants this probably reflects an age rather than device difference. Age was the only significant influence over level of information recall when adjusted for gender, cardiac condition and device type (*β*=-0.12; Wald=4.97; df=1; *p*=0.03; ExpB=0.88; 95% CI for ExpB 0.79 to 0.09). High monitors (χ^2=5.55; df=1; *p*=0.02) and systematic information gathering (χ^2=5.01; df=1; *p*=0.03) were also associated with greater recall of information. The odds of a low monitor having lower level recall was 4 times higher than if they were high monitors (59% versus 26%; OR 4.12; 95% CI 1.23 to 13.77). Also, those who were high on heuristic information gathering were more likely to report low level recall than systematic information gatherers (54% versus 20%; OR 4.75; 95% CI 1.14 to 19.84). Unadjusted logistic regression confirmed the correlation between mean monitoring scores (*β*=0.05; Wald=3.83; df=1; *p*=0.05; ExpB=1.06; 95% CI for ExpB 1.00 to 1.12); decision approach (*β*=1.56; Wald=4.57; df=1; *p*=0.03; ExpB=4.75; 95% CI for ExpB 1.14 to 19.84) and knowledge recall (Table 4.23). However, adjusted scores were not significant. Further scrutiny of specific aspects of information received also revealed differences among participants.

4.3.8.2.3 Benefits And Harms Of Accepting And Refusing The Device

The benefits and risks associated with having the device had been discussed with most (47; 94%), whereas the benefits and risks of not having a device was only discussed with thirty (60%) patients. Pearson's chi-square suggests that being in the younger age group (χ^2=6.62; df=1; *p*=0.02) and higher monitoring scores (χ^2=5.92; df=1; *p*=0.02) may increase likelihood of the implications of refusing a device being discussed. Additionally, a recommendation for ICD or CRT-D also influenced the likelihood of discussing device refusal (χ^2=4.86; df=1; *p*=0.05).

4.3.8.2.4 Physical Issues

Thirty six (72%) participants were forewarned of potential physical complications during and post device implantation, such as bleeding, infection and lead displacement. There appeared to be an association between discussion of physical concerns and level of education (χ^2= 7.34; df=2; *p*=0.03) but not occupational status or HL. Engagement with a systematic decision approach (χ^2=4.84; df=1; *p*=0.04) and the device type also appeared to enhance the likelihood of discussing physical issues (χ^2=5.62; df=1; *p*=0.03). CRT-P recipients were less likely to state that they had discussed physical problems such as infection, bleeding and lead displacement despite applying equally to both devices.

Table 4-22 Summary Of Logistic Regression Analysis For Variables Predicting Level Of Information Recall

Covariates	**Unadjusted**					**Adjusted**				
Model	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2
Gender	0.32 (0.79)	0.16	0.69	0.15 to 3.44	0.004	-0.09 (1.03)	0.007	0.93	0.12 to 6.83	0.004
Age (years)	-0.10 (0.03)	8.20	**0.004****	**0.85 to 0.97****	0.26	-0.12 (0.56)	4.97	**0.03****	**0.79 to 0.99****	0.26
Health Literacy	0.25 (0.58)	0.19	0.66	0.42 to 3.99	0.005	1.02 (0.87)	1.37	0.24	0.50 to 15.24	0.26
Known IHD	0.96 (0.59)	2.66	0.10	0.82 to 8.20	0.07	4.00 (1.55)	6.66	0.10	2.62 to 1138.7	0.48
NIDCM	-0.02 (0.74)	0.001	0.98	0.23 to 4.18	<0.001	1.74 (1.53)	1.29	0.26	0.28 to 113.86	0.49
HCM / ARVC	1.25 (1.16)	1.17	0.28	0.36 to 33.82	0.04	1.99 (1.83)	1.19	0.28	0.20 to 266.54	0.51
Device Type	-2.53 (1.12)	5.15	**0.02****	**0.01 to 0.71****	0.19	-1.29 (1.29)	1.00	0.32	0.02 to 3.46	0.53

Table 4-23 Summary Of Logistic Regression Analysis For Variables Predicting Level Of Information Recall

Covariates	**Unadjusted**					**Adjusted**				
Model	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2	B (SE)	Wald Statistic	*p* level	95% CI for ExpB Lower- Upper	Nagelkerke R^2
Monitoring	0.05 (0.03)	3.83	**0.05****	**1.00 to 1.12****	0.11	0.03 (0.03)	0.99	0.32	0.97 to 1.10	0.11
Decision Approach	1.56 (0.73)	4.57	**0.03****	**1.14 to 19.84****	0.14	-1.16 (0.83)	1.98	0.16	0.06 to 1.58	0.16

B regression coefficient SE=Standard Error *p* = Significant at <0.05 CI= 95% Confidence interval for ExpB **= Significant

4.3.8.2.5 Emotional Issues

Emotional concerns were less frequently considered with twenty eight (56%) denying any conversation. Increasing age (χ^2=4.71; df=1; *p*=0.04) and a VT/VF diagnosis (χ^2=7.51; df=2; *p*=0.02) seemed to affect the degree to which discussion around emotional concerns of the device was recalled.

4.3.8.2.6 Social Issues / Home & Work

Thirty five (70%) had the opportunity to discuss social issues such as driving, flying, sports and sexual activity. A diagnosis of NIDCM appeared to influence discussion regarding social concerns (χ^2=10.16; df=2; *p*=0.01). Twenty four had discussed specific concerns regarding the possible impact upon daily work and home activities. There was an age related difference in the extent to which device impact upon work and home activities was discussed (χ^2=5.06; df=1; *p*=0.04). A recommendation for ICD or CRT-D was more likely to generate discussion regarding social issues (χ^2=9.18; df=1; *p*=0.006) and marginally associated with an increased likelihood to discuss work and home activities (χ^2=4.81; df=1; *p*=0.05) than CRT-P.

4.3.8.2.7 Source of Information

Unsurprisingly, the younger participant group were far more likely to access information from profession specific websites than older people (χ^2=10.68; df=1; *p*=0.002). Furthermore, high monitors were more likely to source additional information from the ICD specialist nurse (χ^2=6.80; df=1; *p*=0.01), friends (χ^2=5.17; df=1; *p*=0.04), google (χ^2=6.60; df=1; *p*=0.02), patient forums (χ^2=8.00; df=1; *p*=0.006) and professional websites (χ^2=12.35; df=1; *p*=0.001). Conversely only low monitors indicated ‘no further information required’ (χ^2 =8.11; df=1; *p*=0.005).

Only two (4%) participants indicated that they had not had the opportunity to discuss any of the issues. Information recall was not significantly associated with any other socio-demographic or situational variables such as marital or occupational status, cardiac condition, symptom severity, recommending site or decision to accept or refuse. The survey nature of Strand 1 precludes the opportunity to assess actual knowledge and understanding. However, it does illustrate that younger age, higher monitoring and systematic information processing were associated with a higher level recall of information received.

4.3.9 Summary Of Strand 1 Findings

In summary, the significant findings in response to the Strand 1 research aims and objectives are presented here.

Aim 1: To determine whether an association exists between socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret.

To discover whether a relationship exists between demographic characteristics and / or situational factors and self-reported coping style;

- There was an inverse relationship between increasing age and decreasing monitoring scores
- 70% of those diagnosed with known IHD were in the older age group (>66 years). Diagnosis of known IHD was associated with lower mean monitoring scores
- Conversely those with inherited cardiomyopathies were <65 years. Inherited cardiomyopathy was associated with higher monitoring
- Participants were generally less clear about their rhythm history. Those who reported VT / VF were in the younger group
- Educational level and occupational status were independently associated with monitoring scores. When combined to provide an estimate of aptitude for health literacy (HL), lower level HL was associated with lower level monitoring.

To explore whether demographic, situational and coping style factors influence the patients approach to decision making;

- Older participants (>66 years) were more likely to engage solely in heuristic information gathering than the younger group
- Younger participants were more likely to engage in systematic information gathering than older participants
- The odds of the higher aptitude for HL group adopting a systematic approach was 4 times higher than for the lower HL aptitude group
- Known IHD was associated with heuristic information gathering only and HCM / ARVC and VT / VF with systematic information gathering
- Participants with higher monitoring scores were significantly more likely to adopt a systematic decision approach.

To determine whether demographic difference, situational context, coping style and decision approach have an effect upon acceptance and refusal of CRMD therapy;

- ❖ Device refusal (n=3) was associated with being younger, inherited conditions and high monitoring.

To investigate whether socio-demographic characteristics, situational context, coping style, decision approach, acceptance or refusal had an impact upon decisional regret;

- ❖ Reports of decisional regret were low
- ❖ Demographic and situational characteristics, coping style, decision approach and acceptance or refusal did not affect decisional regret.

To establish whether there is an association between the degree of match between desired and actual level of involvement, the final decision and decisional regret;

- ❖ Men reported a greater desire for active control over decision making than women though gender was not associated with actual control
- ❖ Age was not associated with decisional preference but younger participants were more likely to report actual active engagement than the older group
- ❖ There was a weak link between low monitoring scores and a preference for passive decision making but not for actual decisional control
- ❖ 62% of the participants exhibited a complete match between desired and actual decision control. Only 10% displayed a significant mismatch
- ❖ Decisional control match was not significantly associated with any of the variables included in this study.

Aim 3: To examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

To determine whether individual characteristics, coping style, and approach to decision making influenced the level of knowledge acquisition and recall;

- ❖ Increasing age, a CRT-P device, lower monitoring score and sole reliance upon heuristic information gathering was associated with a lower level of information recall. Age was the dominant factor when adjusted for other variables
- ❖ Discussion of potential physical, social and work related issues was recalled by over 70% of participants, whereas emotional concerns were less frequently recalled, with 56% denying any conversation

- Younger participants and high monitors were more likely to access further information from websites and other sources whereas those who did not require further information were all low monitors.

Chapter 5 is concerned with the qualitative Strand 2 of this MM inquiry. It will provide the rationale and a detailed analysis of the research methods selected to undertake phase 1 of Strand 2. In phase 2, Framework Analysis (Ritchie and Spencer, 1994) will be employed to organise the data and interpret the findings. The process will be carefully described and findings presented in rich narrative form.

Chapter 5
Strand 2 Methods And Findings

5.1 Introduction

In line with the planned concurrent mixed methods strategy, the qualitative Strand 2 was designed and implemented alongside Strand 1. Chapter 5 presents the methods and findings of the qualitative Strand 2 of this MMR study (Figure 5.1).

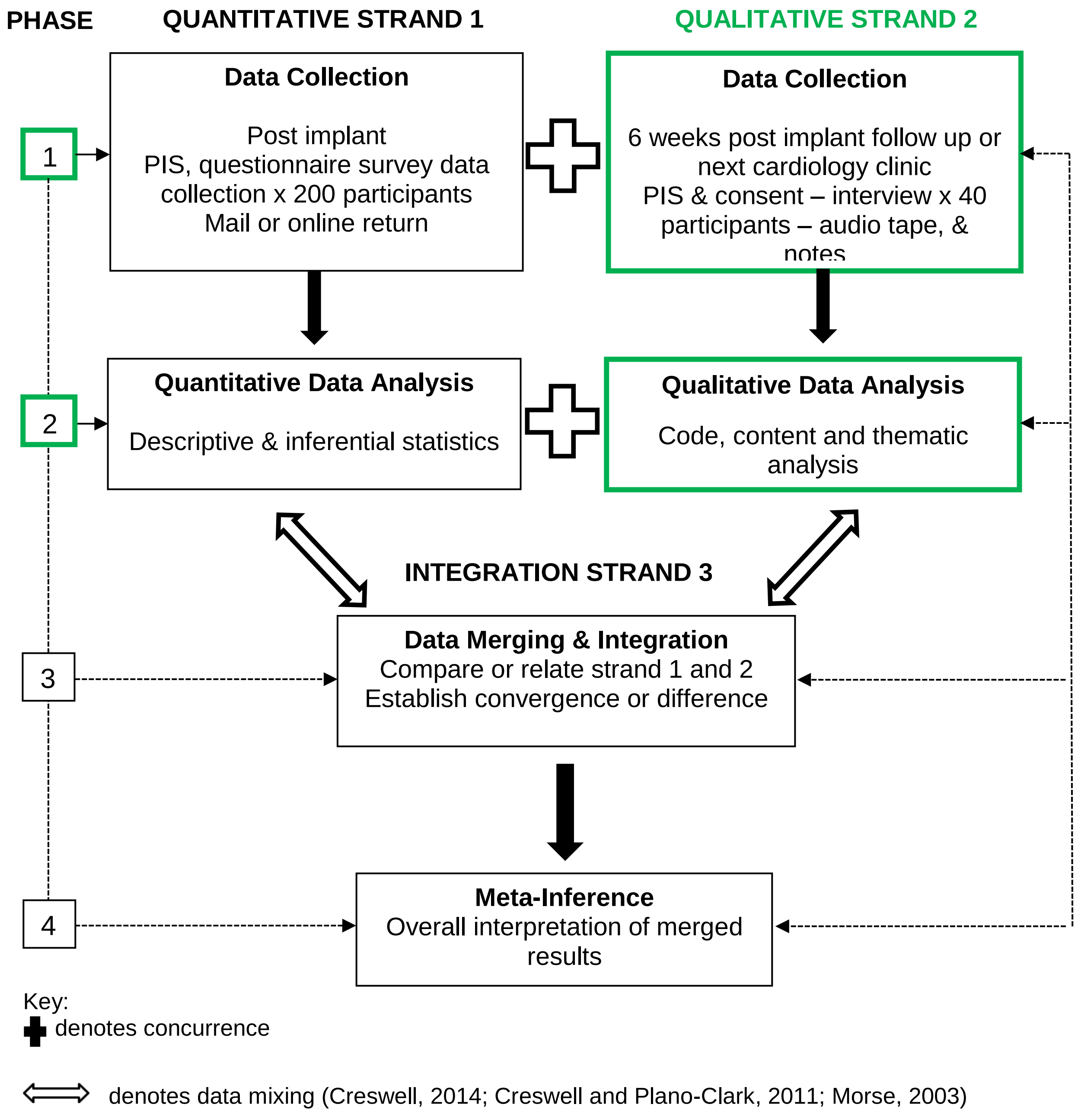

Figure 5-1 Concurrent Parallel, Convergent Mixed Methods Design – Strand 2

Strand 2 adopts a qualitative approach to investigate aims 2 and 3. The research aims were populated with a number of objectives to provide clarity and structure for this phase of the project.

Aim 2: to develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed.

The objectives were;

i. To explore how patients, respond to the initial recommendation for primary prevention CRMD and determine whether it affects their engagement with decision-making
ii. To investigate the extent to which CRMD patients engage in heuristic and systematic information gathering
iii. To examine the extent of collaborative decision-making evident in current local practice
iv. To determine what factors are perceived by the patient to influence the adopted decision approach, acceptance or refusal and decisional regret.

Aim 3: to examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

The objectives were;

i. To discover whether the patient-professional interaction influenced knowledge and understanding and device acceptance or rejection
ii. To identify whether patients have enough relevant information about their cardiac condition, device indication, role function, benefits and potential complications to reach a desired decision and provide informed consent.

5.2 Strand 2 Methods

Strand 2 developed concurrently alongside strand 1. This enabled a more detailed exploration of the decision-making experience of a sample of the survey participants.

5.2.1 The Sample

There is little guidance on sample size for the qualitative component, though six to twenty four participants are considered appropriate for individual interviews (Proctor et al., 2010; Teddlie and Tashakkori, 2009). Therefore, a purposive sample was gathered to generate sufficiently detailed and focused data which was comparable and transferable. All participants who had completed a Strand 1 questionnaire were therefore eligible for participation in Strand 2. The intention was to draw the sample consecutively until the point at which data saturation, whereby no new ideas or information emerged from the interview data (Holloway and Wheeler, 2010; Gerrish and Lacey, 2010). Twenty self-selecting interviewees satisfied the inclusion criteria and data saturation. The inevitable trade-off between self-selection and heterogeneity was acknowledged. Also, a caveat to data saturation rests with the unequal ratio of men to women and acceptors to decliners. Initial transcript scrutiny suggested that data saturation had been reached on completion of interviews with 11 men and 5 women, including 13 who had accepted and 3 who declined a device. Two further interviews with men who had accepted a device, failed to reveal any new information signifying the end of Strand 2 data collection. However in view of the small number of female and device refusal candidates, a decision was made to continue to selectively recruit from these groups should the opportunity arise. Completion of two further interviews with women gave confidence to the view that data saturation had been reached. Seventeen interviewees had accepted the device. It was hoped that any cases who had declined a device could be targeted for interview at their next cardiology appointment, though unfortunately this did not materialise. Therefore only three interviewees had declined CRMD reducing the prospect of data saturation among this group. The inclusion criteria applied at the questionnaire stage governed the interview strand. Although the ability to understand and communicate in English was a pre-requisite it was acknowledged that family members or friends could provide translation to complete the questionnaire, and enable inclusion of black and minority ethnic (BME) groups in Strand 1. However, there was a lack of available resource for translators or interpreters to facilitate interviews or transcription. Thus, an ability to understand, communicate and sign the consent form written in English was a pre-requisite for Strand 2 participation. The exclusion of non-English speaking people from Strand 2 therefore limits the generalisability of the findings.

5.2.2 The Semi-Structured Interview

Face to face, semi-structured interviews were conducted to explore the patient experience of decision-making in a more detailed and complementary manner (Creswell and Plano-Clark, 2011; Creswell, 2009; Teddlie and Tashakkori, 2009). A topic guide was devised in partnership with the three device recipients involved in the survey design (Appendix M). It included a limited number of questions and prompts based upon the conceptual map devised from the scoping review (Chapter 3) and related to the Strand 2 objectives. This was to maintain some structure, ensure that pertinent issues were covered and encourage coherent responses. The intention was to gather a detailed examination of the context in which participants reached their decision, and so develop a more meaningful understanding of the information gleaned from the questionnaires. This was to elicit greater insight in to patients' thoughts and feelings and so provide a broader picture of their experience of decision-making from recommendation to decision. The first three questions focused upon the presentation of symptoms to device recommendation. The aim was to glean a sense of the patients' experience and determine the degree of understanding of their underlying cardiac condition, severity of illness, symptoms, perception of risk and role of CRMD. The next three questions focused attention upon how patients made their decision, their thoughts, feelings and actions to explore individual and collective processes, and reveal any potential heuristic and systematic information processing tendencies. Questions seven to ten aimed to glean a sense of the where, when, how and from whom patients received information, with a view to determining the extent of systematic information gathering, patient professional interaction and information transfer. Other questions focused upon factors perceived to have influenced the decision process and outcome, and whether anything could have helped or made a difference to their decision-making. The guide was reviewed by service users and academic supervisors who were content that the language and structure was clear and logical. Confirmation was received at the first participant interview and no amendments were made. Open ended prompts such as 'how did that make you feel?' were used to '*allow respondents to express their own understanding in their own terms*' p348 (Patton, 2002).

5.2.3 Study Setting And Access

Information pertaining to Strand 1 and 2 was included in the PIS[4iv]. All potential participants were given the PIS when first approached by the direct care team. The PIS clearly stated that voluntary involvement could be for Strand 1 only or both 1 and 2. This was re-emphasised by the PI during recruitment to Strand 1 and a second copy of the PIS was included with the Strand 1 survey. The questionnaire concluded with an

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[4iv] PIS is available in the supplementary information.

invitation to participate in Strand 2 interviews. Participants were asked to express an interest by completing their contact details at the end of the survey. Potential interviewees were contacted via their preferred method to provide further Strand 2 information and arrange a convenient time and place for the interview, to coincide with the next clinic appointment. For most this was at the four or six weeks (site dependent) post implant follow up or the next scheduled cardiology consultation for those who had declined a device. One participant was interviewed at six months post implant due to a non-cardiac treatment regime immediately post ICD implant. Despite some logistical problems created by the scarcity of available space, interviews took place in a private consultation room within or close to the outpatient department or Trust clinical research facility. The purpose and nature of the interview were explained and the PIS referred to at the start of the meeting. All participants acknowledged receipt and understanding of the PIS. Questions were clarified and written consent was gained immediately prior to the interview[8]. Interviews were audio recorded and intended to last for approximately 45 minutes. Supplementary field notes were collected during interviews to capture relevant non-verbal cues that may add further context to the discussion. For example, the use of humour, degree of emphasis or hesitation in answers, and the nature of communication with others who accompanied the participant were used to annotate the interview transcripts.

The interviewees had completed the questionnaire prior to interview however Strand 1 data analysis did not commence until all questionnaires were collected. The Strand 1 survey was not intended to inform the Strand 2 interview schedule. However, the questionnaire was referred to during the interview, but only to gain clarification of some of the answers given where necessary. Partially completed or missing survey data was also collected. Preliminary content analysis of the interviews did occur during Strand 2 data collection but did not inform the subsequent interviews. The original topic guide remained unaltered and was adhered to throughout the interviews. The interviews were recorded onto a password protected audio recorder. Anonymisation of audio recordings (using the PIN allocated to the participant's questionnaire) and verbatim transcription into a password protected word document, stored on the secure University server, occurred within 5 days of interview. Transcripts were checked for accuracy. Audio recordings were permanently deleted once transcribed.

5.2.4 Ethical Considerations

Application and ethical approval for Strand 2 was granted at the same time as Strand 1. The same ethical considerations covered in Strand 1 and detailed in chapter 4 were applied to Strand 2. Ethical issues specific to Strand 2 are presented here.

5.2.4.1 Informed Consent

Written consent[7] for Strand 2 was obtained on the day of but prior to the interview. The opportunity for further explanation and questions was given prior to consent. Capacity to consent was assumed if participants could reiterate the purpose of the study, their role and extent of involvement and opportunity to withdraw. Interview participants were required to sign the consent form.

5.2.4.2 Confidentiality, Anonymity And Data Storage

Interviews took place on hospital premises, during office hours, either in a private room within the outpatient department or the clinical research facility. Interviews were audio recorded onto a password protected digital recorder. The audio data was transferred and stored in a password protected file on a secure drive at the University of Leeds for transcription, by the primary investigator (PI) as soon after the interview as possible. Once uploaded, audio recordings were immediately deleted from the recorder. All electronic information was anonymised using the same participant PIN used for the questionnaire and stored in password protected electronic files on the secure drive at the University of Leeds. All paper documentation, including questionnaires, consent forms and additional field notes remain confidential and are stored in a locked filing cabinet in a locked room on the University of Leeds campus and can be accessed only by the PI. Anonymised data collected from the questionnaire and interview transcripts were made available to the researcher and academic supervisors only for the purposes of academic integrity and credibility. Any direct quotations from participants remain anonymised and unidentifiable to all except the PI. Data transfer, access, coding and analysis via the secure drive was carried out on campus or via the University remote access system (Desktop Anywhere). All data was stored according to the University (http://www.leeds.ac.uk/secretariat/data_protection_code_of_practice.html) Code of Practice on Data Protection. All data will be kept for no longer than 5 years post successful submission of the thesis and will then be destroyed by shredding and electronic files permanently deleted from the secure drive.

5.2.4.3 Rights, Risks And Benefits

Participants were informed that interviews would not be longer than 60 minutes. But, time invested by those who participated in the interview could be construed as inconvenient. It was acknowledged that the interview could evoke recall of what was perceived to be a stressful event or provoke feelings and emotions related to self-doubt, a re-evaluation of the decision reached or further uncertainty and dissatisfaction.

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[7] Interview Consent Form is available in the supplementary information.

If a participant appeared to be uncomfortable or distressed in any way, the interview would be adjourned immediately. The PI has many years of experience caring for patients with cardiac conditions including CRMD implantation which could have been drawn upon to provide immediate reassurance. Further to this, the PI would refer the participant to the specialist nurse or physiologist and/or appropriate consultant for further advice if necessary. The interview would only be resumed at the participant's request.

5.2.4.4 Right To Withdraw

Participants were informed of their right to withdraw from the study at any time prior to, during and up to one week following the interview without providing a reason or explanation. They were aware that all data could be removed from the study and destroyed up to two weeks after the interview. After this, data would be anonymised, immersed within the findings for analysis and could no longer be withdrawn.

5.2.5 Qualitative Data Analysis

Various methods of qualitative data analysis exist including analytic induction, constant comparison or discourse, conversation, narrative and framework analysis (Lathlean, 2010). The general principles of framework analysis, originally conceived to facilitate analysis of applied policy research is now an established method in applied health research (Ritchie and Spencer, 2002). It provides a systematic, five stage interconnected, iterative approach to data familiarisation, identifying thematic frameworks, indexing, charting, mapping and interpretation (Ritchie and Spencer, 2002). Figure 5.2 summarises the framework approach used based upon Ritchie et al. (2014). It was selected for this study for several reasons. Firstly, the framework method is not aligned to an epistemological, philosophical or theoretical stance but is described as a flexible, pragmatic 'tool kit' approach (Gale et al., 2013). This accommodated the researcher's philosophical viewpoint. It incorporates all aspects of generic qualitative content and thematic analysis techniques, within a rubric. This provides explicit stages which provide organisational clarity and transparency of the analytical process from descriptive to conceptual categories (Lathlean, 2010; Ritchie and Spencer, 2002). The combination of structure with the fluidity offered by the opportunity to move iteratively back and forth between the stages of analysis was particularly appealing. More specifically, it provided a well-defined, coherent structure for large volumes of 'unstructured' verbatim transcription of interview data.

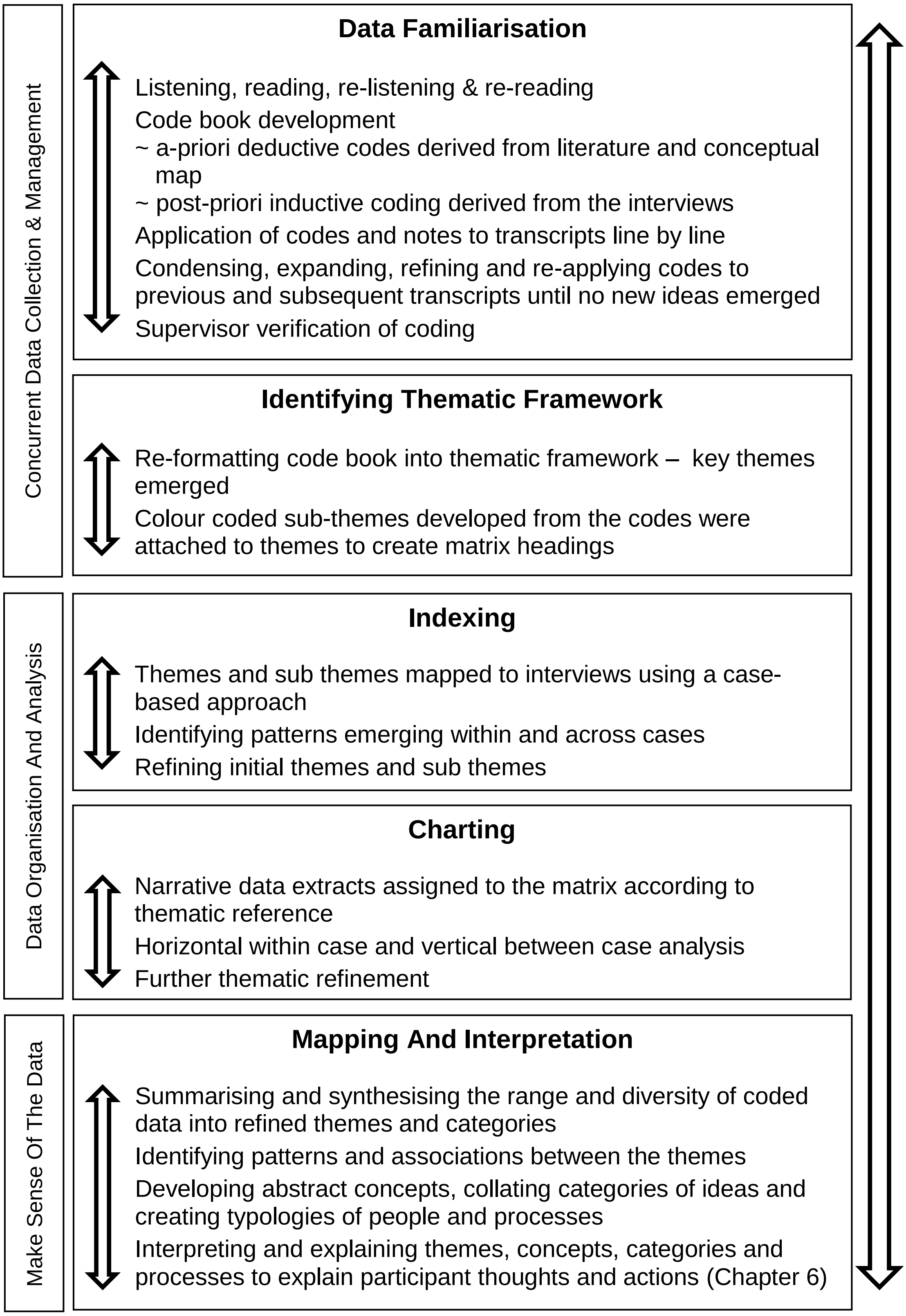

Figure 5-2 Schematic Representation Of The Process Of Framework Analysis

Secondly, framework analysis facilitates comprehensive mapping of the range and nature of a phenomenon such as decision-making (Ritchie et al., 2014). A key feature is that it allows for cross-case and between-case analysis, enabling commonalities and themes to be highlighted across the database, while retaining sight of the original accounts of the participant voice (Ritchie et al., 2014; Gale et al., 2013). Equally it permits systematic, disciplined analysis while retaining and incorporating the creative and conceptual skills required of the researcher '*to determine the meaning, salience and connections'* p310 (Ritchie and Spencer, 2002). Finally, as a consequence of framework analysis, the identification of linkages and patterns within the data may emerge to create typologies of behaviours or attitudes (Ritchie et al., 2014).

5.2.5.1 Developing Typologies

The concept and construction of types, to organise and explain complex social phenomena frequently appears in qualitative research (Ayres and Knafl, 2012; Kluge, 2000). However, there is limited information on how types might be constructed in a systematic and transparent manner (Kluge, 2000). Ayres and Knafl (2012) define typological analysis as;

> *'a strategy for descriptive qualitative (or quantitative) data analysis whose goal is the development of a set of related but distinct categories within a phenomenon that discriminate across the phenomenon'* p901 (Ayres and Knafl, 2012)

The concept of typology is described here as a grouping process based upon the presence of similar characteristics (Kluge, 2000). Elements within each type should be as similar or internally homogenous as possible and the difference between types should be equally evident to ensure external heterogeneity (Kluge 2000). Typologies are characterized by categorization, but not by hierarchical arrangement, and the categories in a typology are related and not subsidiary to one another (Ayres and Knafl, 2012). Authors have described a four-stage approach to typology development within qualitative analysis. The four stages include organising a framework, identifying sources of commonality and variation within the data set, recognising patterns of similarity and difference among the sources of commonality and variation, and reconstructing patterns in to types (Ayres and Knafl, 2012; Kluge, 2000). Therefore, framework analysis provided the ideal tool kit for typology development in this study. The first step involved data familiarisation.

5.2.5.1 Data Familiarisation

Full transcripts were imported into an Excel spreadsheet and line numbers applied to text to facilitate data organisation, ease of reference and aid summarisation and analysis. Plans to export the data into NVivo were aborted to avoid duplication of effort. Contrary to Ritchie and Spencer’s (2002) suggestion that selective familiarisation would suffice at this stage, the data was scrutinised repeatedly in its entirety. Repeated audio listening during transcription and reading of the script, while time consuming, enabled the researcher to become fully immersed in and familiar with the depth and diversity of the original data. This allowed the process of abstraction and conceptualisation to begin, whereby ideas and recurrent themes emerging from the data were coded. For example, the notions of ‘optimism’ and ‘evidence of heuristic thinking’ became immediately apparent. A code book was developed to help capture initial thoughts and concepts[8]. In the early deductive stage, ideas were pre-defined by *a priori* knowledge established from the literature and conceptual map and colour coded red. For example, ‘individual decision-making’ was subdivided into ‘systematic’ or ‘heuristic thinking’. During the inductive phase, the data began to dictate the evolving ideas. For example, the ‘blunting’ code derived from the literature and ‘information avoidance’ emerging from the narrative were merged together. Substantive codes, that is, those relating to incidents or behaviours in response to specific interview questions, were colour coded green. For example ‘what happened next?’ ‘who was the biggest influence’, the initial reaction to the recommendation and knowledge of condition and device therapy were coloured green. Information arising from the narrative concerned with values and emotions such as optimism, desire and denial were colour coded blue. The identifier number and colour allowed the vast data to be labelled and organised into manageable chunks for further analysis. Each transcript was coded line by line for significant words, phrases and ideas to enhance transparency, visibility and transferability (Appendix N). Ideas for further exploration emerging from the data were captured as narrative annotations. This was an invaluable method for capturing thoughts and ideas to support the development and refinement of the emerging theory throughout the project.

The code book developed iteratively as interviews progressed and repetitive scrutiny and analysis of the data revealed new ideas which were then reapplied to subsequent and previous interview scripts (Figure 5.3). Divergent ideas resulted in code expansion whereas similarities were condensed or collapsed to avoid repetition. For example, evidence of blunting 1.2 and information avoidance 17.5 were amalgamated in to code 1.2.

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[8] The Code Book Final Version 4 is included in the supplementary information.

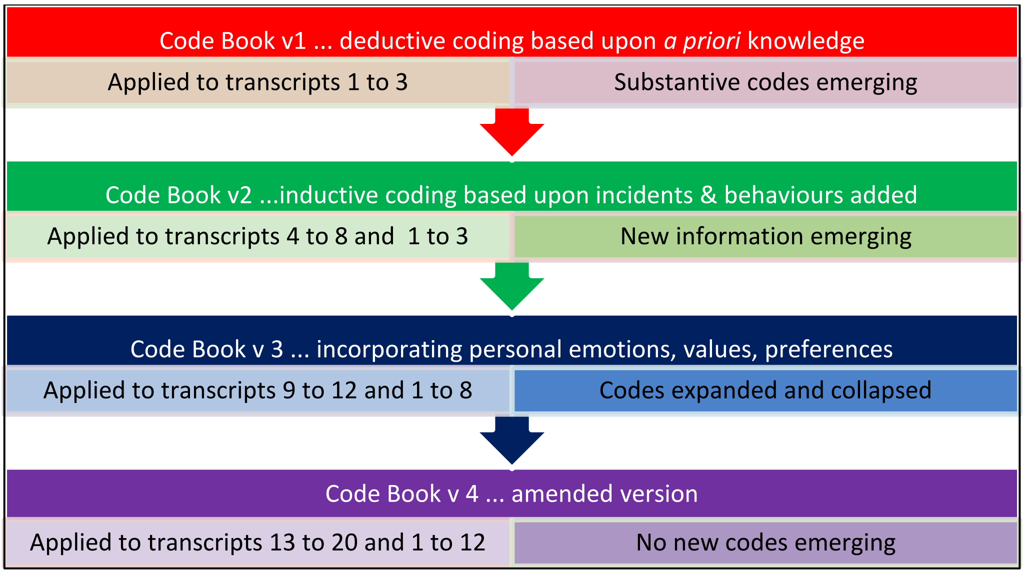
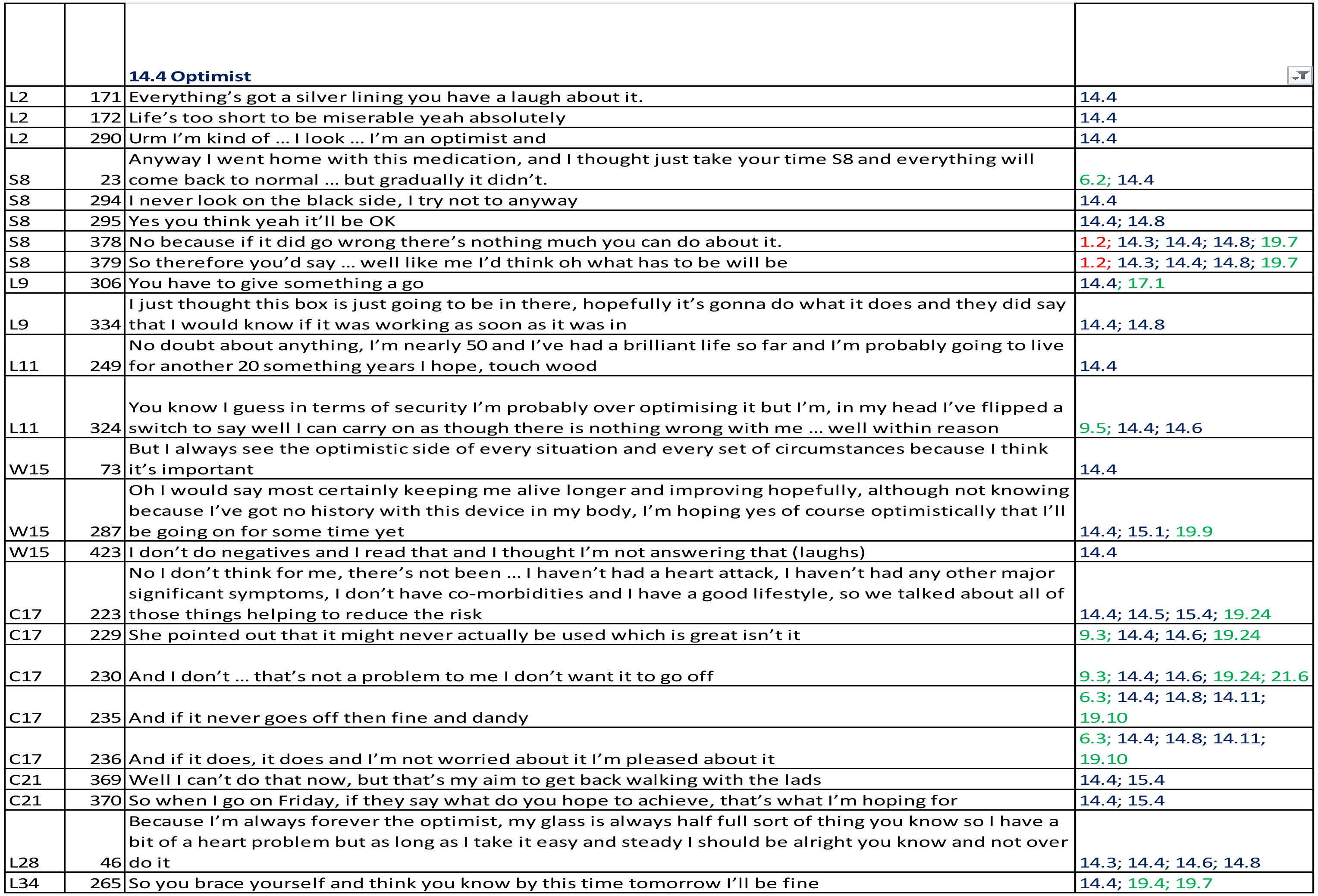


Figure 5-3 Iterative Phases Of Code Book Development

Similarly, referral to personal experience and that of others were combined to form one ‘availability heuristic’ code. As the extent of overlap between codes was realised, a degree of overzealousness in a desire to code every line of narrative for fear of missing something also became apparent. While demonstrating thoroughness, the need to record un-coding or collapsing of codes for transparency was time consuming. Collapsed codes were retained in brackets to provide a transparent trail of coding activity. Coding continued until no new ideas emerged from the data, and the final code book v4 had been applied to each transcript. Data saturation had been reached. Two academic supervisors independently coded four randomly selected transcripts. There was a high level of agreement with the codes identified by the PI. Specific differences related to the overlap of codes. For instance, codes 12.2, 21.3 and 22.12 all related to the impact of devices upon driving and were subsequently amalgamated. One of the supervisors noted the researcher involvement in providing information in response to participant questions and whether this should be logged independently. This subsequently formed part of the evidence to support the level of recall of information during data analysis. The high level of congruence between the independent coders provided further confidence in the rigor and integrity of this stage of data organisation.

A further step, though on reflection not necessary for framework analysis, involved the alignment of narrative quotes to each of the codes to determine the extent of code relevance (Figure 5.4). This step added further weight to the credibility and precision of the coding process. In addition, some instances, for example cognitive ease were not particularly evident and therefore removed from the code book.



		14.4 Optimist	
L2	171	Everything's got a silver lining you have a laugh about it.	14.4
L2	172	Life's too short to be miserable yeah absolutely	14.4
L2	290	Urm I'm kind of … I look … I'm an optimist and	14.4
S8	23	Anyway I went home with this medication, and I thought just take your time S8 and everything will come back to normal … but gradually it didn't.	6.2; 14.4
S8	294	I never look on the black side, I try not to anyway	14.4
S8	295	Yes you think yeah it'll be OK	14.4; 14.8
S8	378	No because if it did go wrong there's nothing much you can do about it.	1.2; 14.3; 14.4; 14.8; 19.7
S8	379	So therefore you'd say … well like me I'd think oh what has to be will be	1.2; 14.3; 14.4; 14.8; 19.7
L9	306	You have to give something a go	14.4; 17.1
L9	334	I just thought this box is just going to be in there, hopefully it's gonna do what it does and they did say that I would know if it was working as soon as it was in	14.4; 14.8
L11	249	No doubt about anything, I'm nearly 50 and I've had a brilliant life so far and I'm probably going to live for another 20 something years I hope, touch wood	14.4
L11	324	You know I guess in terms of security I'm probably over optimising it but I'm, in my head I've flipped a switch to say well I can carry on as though there is nothing wrong with me … well within reason	9.5; 14.4; 14.6
W15	73	But I always see the optimistic side of every situation and every set of circumstances because I think it's important	14.4
W15	287	Oh I would say most certainly keeping me alive longer and improving hopefully, although not knowing because I've got no history with this device in my body, I'm hoping yes of course optimistically that I'll be going on for some time yet	14.4; 15.1; 19.9
W15	423	I don't do negatives and I read that and I thought I'm not answering that (laughs)	14.4
C17	223	No I don't think for me, there's not been … I haven't had a heart attack, I haven't had any other major significant symptoms, I don't have co-morbidities and I have a good lifestyle, so we talked about all of those things helping to reduce the risk	14.4; 14.5; 15.4; 19.24
C17	229	She pointed out that it might never actually be used which is great isn't it	9.3; 14.4; 14.6; 19.24
C17	230	And I don't … that's not a problem to me I don't want it to go off	9.3; 14.4; 14.6; 19.24; 21.6
C17	235	And if it never goes off then fine and dandy	6.3; 14.4; 14.8; 14.11; 19.10
C17	236	And if it does, it does and I'm not worried about it I'm pleased about it	6.3; 14.4; 14.8; 14.11; 19.10
C21	369	Well I can't do that now, but that's my aim to get back walking with the lads	14.4; 15.4
C21	370	So when I go on Friday, if they say what do you hope to achieve, that's what I'm hoping for	14.4; 15.4
L28	46	Because I'm always forever the optimist, my glass is always half full sort of thing you know so I have a bit of a heart problem but as long as I take it easy and steady I should be alright you know and not over do it	14.3; 14.4; 14.6; 14.8
L34	265	So you brace yourself and think you know by this time tomorrow I'll be fine	14.4; 19.4; 19.7

Figure 5-4 Example Of Narrative Quotes Applied To Codes

5.2.6 Identifying A Thematic Framework

The code book provided the basis for a tentative thematic framework to develop in an iterative manner, to structure and facilitate data sifting and sorting. The development of an organising framework fulfils the first step in typology development (Ayres and Knafl, 2012). The initial framework was based upon *a priori* ideas gleaned from the conceptual framework and literature. It was organised around 3 overarching areas of interest, which were the process of decision-making, knowledge acquisition and influencing factors[9]. Twelve themes and several sub-themes were inductively derived from the participant's narrative. Further refinement and organisation of themes and sub-themes occurred during subsequent data analysis (Ritchie and Spencer, 1994). For example, by re-reading coded text in the context of interview narrative, new themes and sub-themes could be added and collapsed where indicated. This allowed themes and sub-themes to mature, for example the notion of expert opinion and that of others began as two themes but eventually collapsed into one 'initial thoughts and actions' theme. Sub-themes, 'availability self' and 'availability others' were merged under the 'availability heuristic thinking' sub-theme.

The final framework v3 was slightly re-structured around the Strand 2 aims[10]. Study aim 2 was to explore the process of decision-making. Five themes concerned with the patient decision-making journey emerged from the interviews. They were the recommendation, initial and subsequent thoughts and actions, collective participation and endorsing the decision. Study aim 3 was to gain greater insight in to the patient physician interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent. The two themes developed were gathering intelligence and knowledge and understanding. Five themes focused upon the influencing factors, including the healthcare professional, faith in technology, device specific issues and concerns, personal characteristics and goals, and biggest influence. Several sub-themes were created to organise the detail within each theme.

5.2.1 Indexing

Indexing refers to the systematic, subjective application of the thematic framework to each interview transcript independently[11]. Many sections of transcript contained more than one theme and sub theme. Therefore, use of colour and numbers was instrumental in highlighting patterns of association within and across the data, and the

9 Examples Of Early Coding And Sub-theme Development v3, 10 Final Matrix v3 and 11 Example Of Indexing are available in the supplementary information.

context in which they were presented. Important sources of commonality and variation within the data were identified during indexing. This is a crucial second element of typology development (Ayres and Knafl, 2012; Kluge, 2000).

5.2.2 Charting

Charting involved removing extracts of narrative from the original transcript and re-arranging them within a chart according to their thematic reference. Three examples of charting are available in the supplementary information[12]. Direct quotes illustrating key terms, expressions and phrases were used in order to keep as close to the original data as possible. Each theme had its own matrix. Each column represented a sub-theme and each row a participant. For clarity, participants were always presented chronologically and the code book reference (v4) was included within the sub themes. This enabled horizontal within case analysis and vertical between case thematic analyses to be undertaken. This facilitated the third step in typology development described by Ayres and Knafl (2012) whereby patterns of similarity and difference among the sources of commonality and variation became apparent. For example, the varying extent of faith and trust in expert opinion appeared to be a factor of different types of decision-making.

5.2.3 Mapping And Interpretation

The final stage of framework analysis and typology development, concerns the abstraction and interpretation of the summarised data, and reconstructing patterns in to types (Ayres and Knafl, 2012; Kluge, 2000). This involved using the framework for thematic and explanatory analysis of the key characteristics identified. The purpose was to map the range and nature of the decision process, create typologies, find associations and attempt to provide explanation as to why some patients accept and others decline CRMD. This was done via a process of reading and cross-referencing content between (vertical) and within (horizontal) the participants' narrative. Characteristics of and differences between the data which re-affirmed, theoretical concepts were identified, and patterns and connections were collated to form more substantive ideas.

During this dynamic stage, the participants' accounts began to reshape the original sub-themes to assume a more nuanced representation of the patient experience from the perspective of this group. That is, higher-order categories were developed and

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[12] Three Examples Of Charting are available in the supplementary information.

abstracted from the data. For example, balancing a desire to prolong or improve life with perceived benefits and harms of device therapy, symbolised the planning stage in the decision-making. Thus, the data developed from the descriptive to a more conceptual level. Furthermore, connections and patterns between the abstracted data became evident. For example, prolonging life and an emphasis upon device benefits signified device acceptance. Whereas, prioritising QOL and a focus upon potential device harms resulted in device refusal. Thus, participants appeared to fit into certain categories of decision-making. So participant perceptions, accounts and experiences were compared for similarities and re-grouped to generate a typology of decision-making. Regular discussion of the framework development, indexing, analytic process and findings with academic supervisors (PM and JM), was crucial to ensuring the credibility and confirmability of the framework analysis. Clarity, concordance and congruence at each step of the process was agreed before embarking upon the next step.

5.3 The Findings

Twenty participants (13 male; 7 female), aged between 34 and 80 (mean 60.3; SD 10.59) years agreed to be interviewed. Eleven had evidence of IHD including AF and / or HF, four DCM (3 were idiopathic), and five had an inherited cardiac condition. Seventeen participants received a device and three declined. Only one participant was recommended for and accepted a CRT-P, therefore there was insufficient data to provide a meaningful comparator group. Table 5.1 shows the age, cardiac condition and device type of those who accepted and declined a device.

Table 5-1 Characteristics Of Interviewees

	Male	**Female**	**Age (Mean / SD)**	**Cardiac Condition**	**Device Type**
Accepted n=17	12	5	61.76 (9.13)	IHD = 10 DCM = 4 ICC = 3	ICD = 10 CRT-D = 6 CRT-P = 1
Declined n=3	1	2	52 (16.7)	IHD = 1 ICC = 2	ICD = 2 CRT-D = 1
Total	13	7	Overall Mean 60.3 (10.59)	20	20

The qualitative findings are presented in two parts to correspond with the two main aims. The first refers to the process of decision-making and the second part is concerned with information exchange and knowledge acquisition.

5.3.1 The Process Of Decision-Making

The first aim was to develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed. Five overarching themes emerged. Sub themes representing similar ideas and commonalities were developed to organise the detail (Figure 5.5).

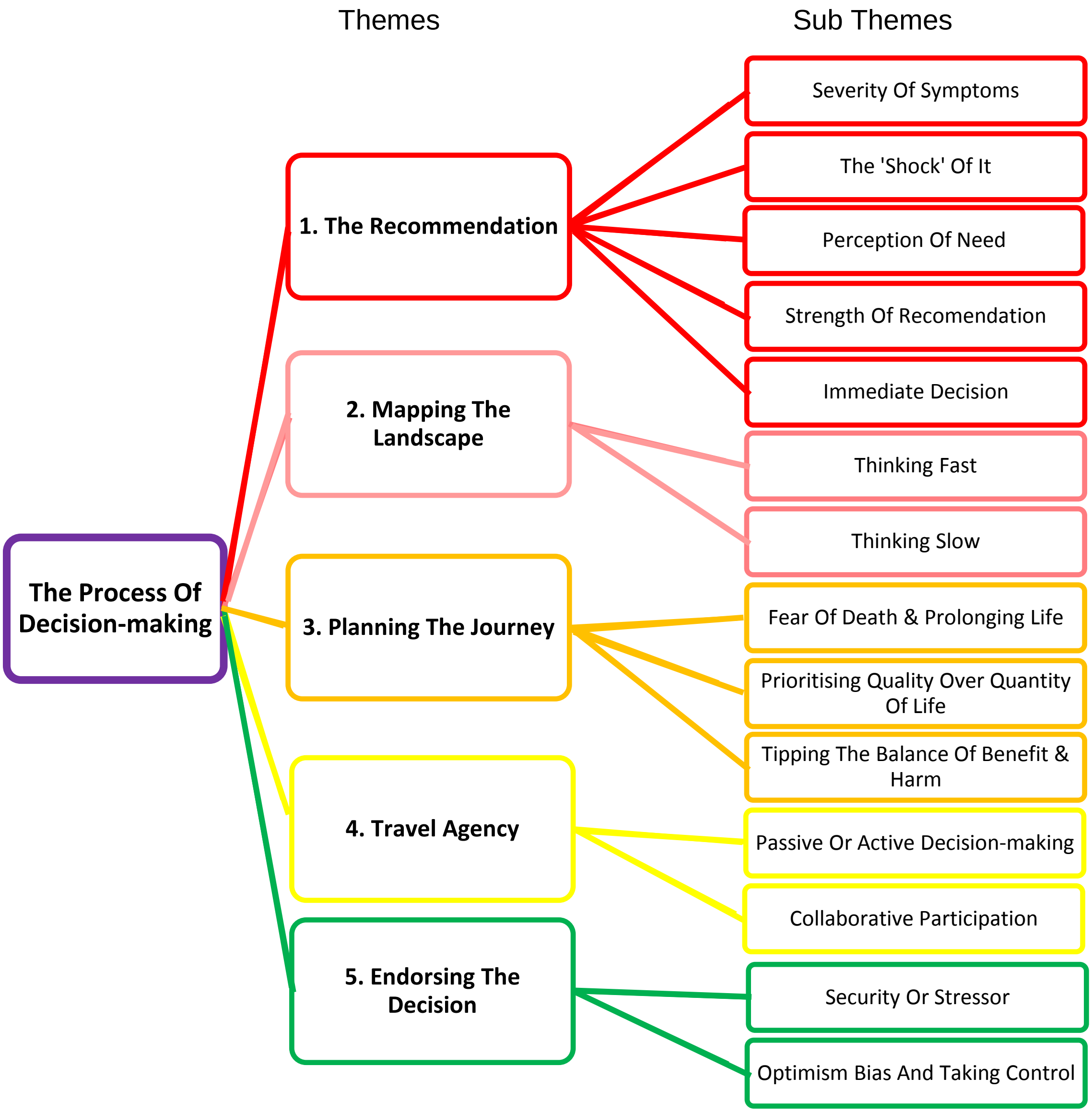


Figure 5-5 The Process Of Decision-making

One objective was to determine what factors were perceived by the patient to influence the adopted approach and device acceptance or refusal. The influencing factors revolved around the healthcare professional (HCP), the technology, personal desires and personal characteristics. Reference to influential factors is incorporated throughout the narrative, to provide a richer description rather than as a separate sub-theme.

5.3.1.1 The Recommendation

In order to place their decision-making in context, participants were asked to recall their experience prior to and during the consultation when CRMD was first recommended.

5.3.1.1.1 Severity Of Symptoms

All but one of the participants described experiencing symptoms such as dizziness, breathlessness and lethargy, prior to the recommendation for primary prevention CRMD. Various adjectives such as '*severe*' '*gasping*' '*extreme lethargy'* were used to indicate the perceived severity of symptoms. The impact of their symptoms upon their physical, emotional and social wellbeing was significant;

> *'I was gradually feeling worse. I had to give up, I've given up a day at work, I have had to kind of limit what I do and I've had to give up things like I used to go to a choir on a Wednesday night. I haven't done that for a couple of years now. I was starting to, beginning to feel a bit low actually. I was starting to struggle a bit'* L4
>
> *'I had to stop on a slightest incline near the end, I'd just run out of gas and then for 2 or 3 days afterwards I was quite symptomatic'* L11
>
> *'57 year old guy who sometimes feels like he's 70'* W12

These participants immediately or eventually accepted the device. However, those who had declined a device described similarly severe symptoms;

> *'Walking up a flight of stairs on to Euston Road at Kings Cross and I would get to the top and I would feel like I was going to pass out'* L22
>
> *'It's like having your chest filled with concrete because you breathe in but there's nowhere for it to go and so you have this panic and at that point you then start to cough and then this liquid is coming up'* L26

Yet they did not consider them to be significant indication to warrant CRMD or they believed that other interventions would resolve them;

> *'I'll have it done when I need it done but I don't feel in terms of my symptoms and the way that the disease impacts on my life that I need to have it'* L22

Personal appraisal of symptomatology, rather than actual symptom experience was associated with a perception of clinical need.

5.3.1.1.2 The 'Shock' Of It

For most, the recommendation was unexpected, though five patients with inherited conditions had some awareness of potential management options and so were partially prepared prior to the consultation. Expected or not, the initial device recommendation (most often from a doctor) aroused a range of feelings. Notably, the defibrillator function elicited a sense of shock, fear, apprehension or a 'surprised' response from over half (12) of the participants. Some described, '*being scared'* S6 or '*gutted'* L9 and the word '*shock*' was frequently used;

> *'You are at risk of sudden death you start thinking phhh maybe it is a little bit more serious'* and *'this sudden death thing it shocked me at first'* L28
>
> '*It did shock me a bit actually'* S35
>
> *'That frightened me to death'* and *'When someone's told you about a cardiac arrest it is a little bit frightening'* S44

For some participants, particularly those who declined the device, the initial recommendation was perceived to be incredulous, threatening and stirred feelings of panic;

> *'they would just bring it up as some kind of threat'* and *'it was my cardiologist saying I think you need one which kind of freaked me out. Then you do feel not great because you are panicking'* L22
>
> *'I was as I said a little bit taken aback that we were now talking about something that seemed to me to be quite intrusive and quite a sort of an almost disproportionate response to obviously what I had felt to be quite a minor thing'* L26

Six participants appeared to have had a more matter of fact attitude towards the recommendation. Some patients also expressed a degree of 'relief' that something other than continued surveillance or sole reliance upon pharmacological therapy was to be done. For these the CRT option presented some hope of an improvement in symptoms. Two ICD recipients were also relieved at the prospect of bradycardia support to enable increased medication to address their symptoms.

Some men and all but two of the female participants described themselves as 'worriers' including the two who refused the device. Some described feeling anxious during consultations;

> *'The worse thing for me is where I feel like my cardiologist thinks that I should have one, that puts me in to a panic and then the worrying and the stress of the worrying gives me palpitations. You've opened that box again of it's a risk'* and

> *‘I’m always nervous before a consultation because literally anything, you don’t know what they are going to say’* L22
>
> *'I went in to some sort of anxiety and I did end up back in hospital with a panic attack'* and *'I was quite not depressed but I was frightened to do anything'* S44

One participant denied being a ‘worrier’, but did appear to do so prior to his device check (pre-interview) and regarding the procedure and return to work;

> *'I don't really stress, do I, not much, no you just take what’s in front of you, if you've got to'* though he did say *'I think I’m allergic to operations'* and *'She (daughter) were there all afternoon to stop me escaping I think'* S6

Whereas, seven men who accepted the device did not appear to be worriers and adopted a more ‘matter of fact’ view;

> *'That (insurance) was done for my wife’s benefit because she panics, too much as far as I’m concerned. You can never panic too much but me personally I’d prefer to say oh it’s alright'* L2
>
> *‘I’m not given to sort of getting all histrionic about things’* L11
>
> *'I don't hit the panic button easily'* and *'I didn't lose any sleep, I wasn't worried and troubled'* W15
>
> *'There are very few things that make me panic and that wouldn't I know what it would be'* W20

5.3.1.1.3 Perception Of Need

The recommendation confirmed the gravity and inescapability of their condition;

> *'You have the realisation that it actually applies to you and you talk about the risk of sudden cardiac death'* L11

Most of the participants recommended for a defibrillator acknowledged their increased risk of SCA and an appreciation of clinical need. The feeling of enhanced risk was evident among the participants who had declined, though it did not appear to translate in to an appreciation of need;

> *'Well I nearly said to them when they told me am I gonna, when am I gonna die then when is it gonna happen'* L9
>
> *‘You have a bad incident of VT and your dead and that was a bit you know jarring'* L26

At the CRMD recommendation, participants were confronted with an increased, albeit uncertain and unquantifiable but nevertheless greater than average risk of SCD. This is accompanied by the knowledge that primary prevention device therapy presents a brutal opportunity to abort SCA. In the wake of this realisation, the participants had to consider the degree to which they were prepared to embrace technology to help alleviate some of the uncertainty and threat. They had to contemplate their future with or without a device.

5.3.1.1.4 The Perceived Strength Of Recommendation

The impact of the perceived strength of recommendation upon device acceptance was not clear. An appreciation of an elevated risk of SCA and clinical need, reinforced by the perceived strength of recommendation was a persuasive factor for some;

> ‘*The guy that says if you’ve got one fitted it’ll stop imminent death that kinda swung it’* L2
>
> *‘Nurse said I would like you to have it done and Dr X is going to have a word with you as well and he wanted me to have it done and then Dr Y said I think you should have it done so’* S6
>
> *'If they sort of pussy footed about it you’d maybe think oh I don’t really need it but because they are blunt and they come out and say it as it is well then you react to as it is you know, or that’s how I was anyway* L28

Conversely, the perception of a relatively weak initial recommendation was also evident among some who accepted a device;

> *‘She says you can get them that’s just a pacemaker and you can get them where they’ve also got the defibrillator. She says in your case I don’t think you’ll need that but if it’s there and you do actually go in to cardiac arrest at least it’ll get you going again basically’* W18

Those who declined a device perceived the strength of recommendation to be weak. For example;

> *‘Nurse initially made my mind up when he said I didn’t have to have it’* L9
>
> ‘*There’s no new evidence to me as to why I should have one put in now’* and *'I don’t think it’s necessary at the moment’* and *'It’s only factoring in at the moment because it’s so, to me weak. You know if I need it I’ll get it done'* L22

and L26 stated;

> *‘I didn’t get the impression that he was actively pushing it, he didn’t give me the recommendation which I would have taken very seriously had he done. I didn’t get a sense from any of the three doctors that I spoke to that their professional judgement was that I should do this’.*

Therefore, perceived uncertainty and indecision by the experts may serve to reinforce device refusal;

> *‘You’ve got doctors saying to you well it could be, it might be and they are saying well it could be and it might be and then they are saying well because it could be and might be lets now go to the next level and I’m saying wow wow wow so I think that was part of it'* L26

Immediate or eventual device acceptance was generally associated with a recognition of clinical need and perception of a strong recommendation for most. Those who declined remained unconvinced.

5.3.1.1.5 The Immediate Decision

The initial response triggered an immediate, impulsive decision at the point of the recommendation. S6 states ‘*I told them straight away that I wanted it done’* three times during the interview and L4 says;

> *'Even before I’d spoken to ICD Nurse I think I had decided that I was going to go ahead with it'* L4

Similarly, the decision to decline occurred spontaneously;

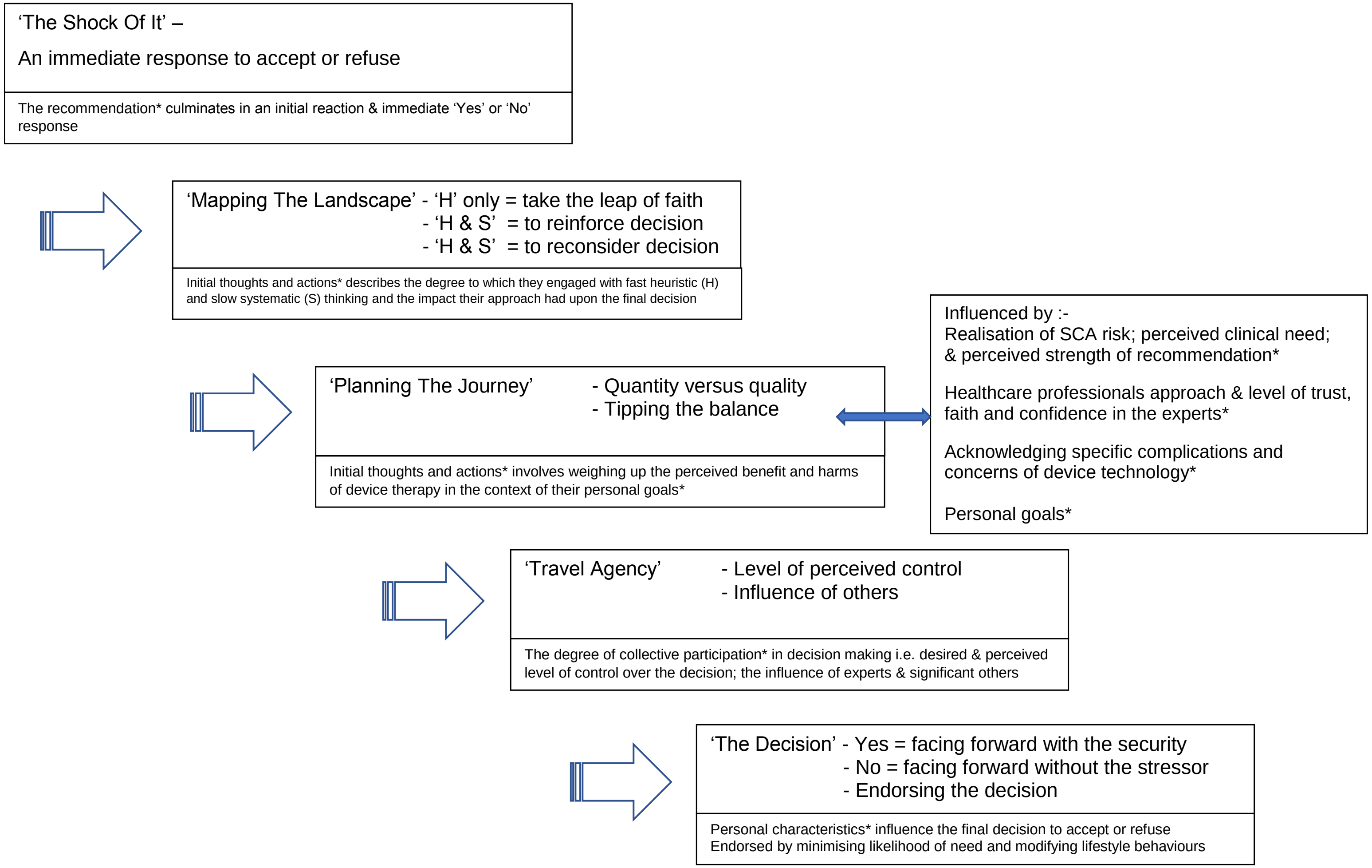
> *'I just didn’t want it because I’ve seen them and knowing the person I was and I thought no its going to ruin my life, I don’t want the defib, I was adamant I didn’t want it’* and *'I never even thought about it I just knew for the definite that I didn’t want it'* L9

On receipt of an unexpected admission letter for ICD implantation, the immediate response was, ‘s*o of course I said no I’m not agreeing*’ L22.

Likewise, another appeared to be certain of his decision from the initial recommendation saying;

> *‘I approached those meetings already slightly negative’* L26

The initial decision remained resolute for 18 (90%) participants, though not so for 2 patients who subsequently changed their mind. Despite the initial reaction, the recommendation then triggered a more considered process of decision-making for some, but not all. The analogy of a journey is used to explain the process of decision-making experienced by this group of participants. Figure 5.6 illustrates the interpretation and transformation of sub-themes into the conception and visual representation of the decision-making process.



‘The Shock Of It’ –

An immediate response to accept or refuse

The recommendation* culminates in an initial reaction & immediate ‘Yes’ or ‘No’ response

‘Mapping The Landscape’
- ‘H’ only = take the leap of faith
- ‘H & S’ = to reinforce decision
- ‘H & S’ = to reconsider decision

Initial thoughts and actions* describes the degree to which they engaged with fast heuristic (H) and slow systematic (S) thinking and the impact their approach had upon the final decision

‘Planning The Journey’
- Quantity versus quality
- Tipping the balance

Initial thoughts and actions* involves weighing up the perceived benefit and harms of device therapy in the context of their personal goals*

Influenced by :-
Realisation of SCA risk; perceived clinical need; & perceived strength of recommendation*

Healthcare professionals approach & level of trust, faith and confidence in the experts*

Acknowledging specific complications and concerns of device technology*

Personal goals*

‘Travel Agency’
- Level of perceived control
- Influence of others

The degree of collective participation* in decision making i.e. desired & perceived level of control over the decision; the influence of experts & significant others

‘The Decision’
- Yes = facing forward with the security
- No = facing forward without the stressor
- Endorsing the decision

Personal characteristics* influence the final decision to accept or refuse
Endorsed by minimising likelihood of need and modifying lifestyle behaviours

Figure 5-6 Making Visual Sense Of The Process Of Decision-making

* Reference to sub themes

5.3.1.2 Mapping The Landscape

Although a quick decision was initially made, for the majority it was generally not based upon prior knowledge or preparatory information gathering before the recommendation. ‘Mapping the landscape’ explains how the initial thoughts and actions that followed the recommendation evolved into the identification of distinct decision approaches. The participants described examples of fast, heuristic thinking based upon immediate access to information either from the expert or recall of their personal experiences or that of others. Four distinct types of decision-making became apparent, distinguished by the degree to which they sought further information to facilitate informed consent and the ultimate decision to accept or decline.

5.3.1.2.1 Thinking Fast

When participants were asked to reflect upon their immediate thought processes, without exception, everyone had valued the express opinion of the cardiologist(s), ICD and HF specialist nurses. Some had explicitly requested the expert’s opinion;

> ‘*I said you’re still in a more informed position than I am what would you do? And he gave me his’* L11
>
> *‘I said if you were in my position would you have it fitted, he said, yes I said well I’d be a fool to go against that advice, so I went with that’* L27
>
> ‘*He basically said in his opinion this was probably the correct route’* L34

Others implicitly accepted that the expert’s recommendation must be the ‘right thing to do’ for example;

> *‘They wouldn’t have suggested it if there wasn’t a requirement for it’* W12
>
> *'You just think well yeah I’ll have to go with it you know and do what it says sort of thing'* L28

However, the value placed upon expert opinion appeared to differ among the participants and may have influenced their approach to decision-making. Furthermore, it did not necessarily translate in to device acceptance. Uncritical acceptance and immediate submission to the expert’s recommendation was evident among 8 device recipients. They explicitly described having faith, trust and/or confidence in the expert’s opinion;

> *‘I couldn’t go against, the way I think about it is if you are talking to a doctor and a doctor explains some’at to you and it sounds good why would you think of, why would you even think of saying no. I have that trust in the doctor’* L2

> *'She's not bothered then I'm not bothered, when you are dealing with people in the know, if they say to you there's no worries, there's absolutely nothing to concern yourself about. Whatever you are doing you put your trust in people don't you, we all have that leap of faith don't we'* W15

They referred to previous experiences which served to reinforce their '*leap of faith'*. Immediate referral to previous personal experience such as bradycardia pacemaker insertion or open-heart surgery, had a positive impact upon the decision believing device implantation could be no worse;

> *'I've had a triple heart bypass, I was in a month with that, now I'm thinking I'll be going in, they'll put me to sleep, they'll do it and that'll be it but it didn't work out that way'* S8

In this study, the experience of others, including TV, radio, family members, friends and acquaintances, other patients and forums was also frequently recalled. This had a positive impact upon the decision for almost half the group;

> *'I've a cousin in Ireland, he had a defib, I looked at him and thought well he hasn't got a bad life'* L2
>
> *'I've got a friend in the village, she's 86, X she does the walk for life. That made me think look at X at 86. If it can help me with my quality of life then I'm 100% for it'* L3

Yet in further conversation both appeared to have a pacemaker, not a defibrillator. Conversely, recollecting the experience of others did have a negative effect for some participants, though not necessarily enough to halt the leap of faith, for example;

> '*We actually watched a programme, that's been doing the rounds on channel 4 about the Asian gentleman who went in and it kept shocking him every seven minutes because it had gone faulty apparently or they thought it had gone faulty. He'd actually watched that before he had it done and he says I'm not having it done now, I said, yes you are'* W18's wife.

Furthermore, this group of participants expressed no desire, made no effort or actively avoided information gathering beyond that received from the experts. When asked whether they had looked up more information or 'googled' the device, they responded;

> *'I don't google. A little bit of information is a dangerous thing I think. I'd better just rely on the experts'* L3

W15 said;

> *'I haven't yet, no but that's a good point, I could have googled it because I've got all the tech. I suppose me, best you don't know'*

> ‘*I didn’t do any research at all, no just my gut feelings and discussions with my wife’* L27

Some even denied receiving or reading the written information given;

> *‘No I didn’t. I didn’t have any information like that it was just verbal'* L3

> ‘*Err probably scanned them, scanned through them, they’re still in my bedroom probably'* L27

Several respondents stated that they did not want any further information than that received from the experts;

> *‘I’d already made my mind up that was available and that was more than adequate. What I got told outweighed anything that I could be told against not having one, balance wise’* L2

> *'There didn’t seem to be any cons to having it done. I don’t know whether there are any because nobody mentioned that there could be problems. I said yes I think it can only be good, you know from the information that I have'* and *'That seemed adequate I don’t think there was anything else he could have explained except the questions I’ve asked you'* L3

The latter part of the sentence illustrates the evident lack of knowledge or recall of information received prior to the implant. These participants used various expressions to describe a ‘*leap of faith’*. Having received the initial consultation information and advice, fast, heuristic thinking dominated an apparent uncritical acceptance of the device recommendation without exploring the implications further.

5.3.1.2.2 Thinking Slow

In contrast, intuitive thinking triggered a period of slow, systematic information gathering and processing among the other twelve participants. This served to either ‘*reinforce*’ their initial thoughts to accept or decline or resulted in hesitant deliberation and ‘*reconsideration*’ of their initial decision. For 10 participants, referral to expert opinion and previous experience was supplemented by systematic information gathering which then served to reinforce their initial decision. The emphasis upon expert opinion and their own or others previous experience differed from those who took the leap of faith. The degree of trust and confidence in expert opinion was evident but not as emphatic or obvious among this group and did extend to a degree of reticence;

> *‘You hope that the expert does have some credibility in their recommendations don’t you, I’m also aware that some are better than others’* C17 (Accepted)

L26 suggested that a lay perspective would have been appreciated if available;

> *'I don't need to actually sit in front of someone who has the word doctor, or Mr or cardiologist expert in front of me, someone who would be able to sit with me in lay terms'* L26 (Declined)

L22 describes persistent reference to device implantation at every appointment and acknowledges expert opinion;

> *'To me it was my cardiologist saying I think you need one which kind of freaked me out because obviously you know I take their opinion very seriously because they are the experts'* and *'I think there would be a point where I would almost defer to my cardiologist because they are the experts'* L22

Despite this, L22 declined a device. There appeared to be a mismatch between believing in and acting on expert opinion. Expert advice appeared to fail to meet certain conditions or agree with the participant's opinion and therefore had little or no apparent impact upon the decision. When asked what if any factors might influence a change of mind, L22 said;

> *'So most important it would be my cardiologist saying to me I think you should have it for these reasons and having kind of evidence-based reasons'*

Yet it was unclear what the *'evidence-based reasons'* would be.

Previous personal experience or that of others was also referred to, but these participants were more likely to recall negative experiences;

> *'Mum's husband died when he had a pacemaker fitted he got an infection on the leads, that's what he died of so that was at the back of my mind'* S35 (Accepted)

The negative experience appeared to be instrumental in deterring one participant from accepting the device;

> *'I mean as a kid I stuck my finger in the light switch, in the bloody light bulb yer know changing a light and I got a shock and I wouldn't go near it again and so obviously if the defibrillator is going to work like that I won't bloomin' go near that again'* L9

L9 also recounted;

> *'My friends got a defib and a pacemaker together and she is bad when it triggers off and I thought I can't do that, I can't have that'* and *'I'd seen them on casualty and so I knew that when they give you a shock, they give you a shock as your whole body goes rigid and I thought, no if that was to happen to me outside I'd be mortified'*

Unlike those who took the leap of faith, these participants invested time to systematically gather information to '*reinforce their decision'*. Notably, they all took time to refer to reputable sources including British Heart Foundation (BHF), Cardiomyopathy Association (CMA) UK, online risk assessment tools, Medtronic and other internet sites which were used to independently gather additional information to supplement that received from the experts, support their final decision and inform their consent;

> *'I just did a google search and then went on anything that had come up umm Heart foundation is the main site that I tend to rely on for accurate stuff, I try and stay off forums'* S35

> *'I've been on the British Heart Foundation and Cardiomyopathy UK which is brilliant and I'd looked at things on there I thought I'll just try and stick to looking at them if I need to know anything'* S44

The decision to accept (n=7) or decline (n=3) further differentiated this group. Those who declined the device also sought further information to reinforce their decision;

> *'I think everything ICD Nurse said just made me think no my instinct is correct'* and *"It's been brought up a number of times and I've found out various information about it and gone to various different people about it'* L22

> *'Online, obviously consultant has been good, I'm one of these guys who kind of likes to ask questions and find out and manage my own health. I had more questions having done a bit of reading about the device and I'd read about people who'd had it and I had more specific questions about the nature of risks I mean consultant had been very upfront and he said yes it's a problem'* L26

Generally, information gathering served to reinforce the initial decision to accept or decline a device.

Two other participants also referred to the expert's opinion, previous experience and systematic information gathering, though they were more hesitant in their deliberation and considered a change of mind before reaching a definitive decision to accept. One participant was initially unsure, having previously 'parked' the potential need for device therapy;

> *'You know you talk to people with these inherited conditions, you've got two choices, you can either learn to live with it or you can, not ignore it but sort of park it out of the way so I played it down'* L11

The other had initially accepted the device on expert advice and heuristic thinking;

> *'He had pretty much made his mind up before I went in that this is what probably needed to be done. He basically said in his opinion this was probably the correct route'* L34
>
> *'I play in a local bridge club and a guy down there had had one fitted I sort of had a chat with him and you know the general opinion seemed to be you know this is probably the right way to go, so yes I was reasonably well sold on it at this point'* L34

However, further information caused them to hesitate and '*reconsider their decision'*. Having had a change of mind, both eventually accepted device implantation.

The impact of fast heuristic and slow systematic information processing differentiated the participants in this study into groups. Heuristic thinking was evident across the transcripts, whereas engaging with active information processing was specific to a type of decision-making. Heuristic thinking did not appear to influence the speed of decision-making, but it may have affected the final decision to accept or decline. Generally, information gathering served to reinforce the initial decision to accept or decline a device. However, further information could divert thinking away from the initial decision and result in a period of hesitation and reconsideration of the decision.

5.3.1.3 Planning The Journey

Planning the journey describes the ways in which participants internalised their decision. The type of decision-making was distinguished by personal priorities in terms of quantity and quality of life and the perceived safety and risks of their journey. To a greater or lesser extent, the participants also considered the potential benefits and harms of accepting 'enhanced protection'. The decision was balanced upon the degree to which they were prepared to relinquish some control to the 'safety' of device therapy or retain a sense of self-determination without the restrictions imposed by technology.

5.3.1.3.1 Fear Of Death And Prolonging Life

The overwhelming impression was that a leap of faith resulted in an impulsive decision to accept based upon fear of an early SCD;

> *'This was like a matter of life and death, wow, this is just a whole new ball game now yeah and that kinda stuck with me'* L2

When asked, those who had made the leap of faith did not appear to have considered the pros and cons of having versus not having a device in any detail;

> *'If they'd have said well the disadvantages of having it outweighs the thing that it's going to do I'd have probably still gone along the lines and had it done because in the end it could possibly save my life'* and *'So as soon as they said you have a chance of dying no matter how small it was, if they could do something that would prevent that*' L28

They were also less likely to evaluate potential benefits and harms from a device specific perspective, such as living longer versus infection risk. Recipients who did consider potential benefits and harms were confident that the potential capacity to save their life outweighed risks, though these were not articulated in any detail but rather described as 'minimal' for many. There was a general sense of better to have than to not have;

> *'There's always the potential with anything manmade giving a problem however they're so slight or like 1 in so many thousand times it could happen, you know I mean it's manmade and anything manmade there's always an option, a chance of something happening to it so I just kinda took all that on board'* L2

> *'The risks of having it in I saw were minimal and I could probably see the potential benefits of having it I thought well if I don't have it and something happens, I'm going to regret that decision'* L27

The participants who reinforced or reconsidered their decision, appeared to contemplate the potential consequences of device therapy upon their quality of life. Responses referred to 'living with' versus 'dying without' or 'improving symptoms with' versus 'worsening symptoms without', and encompassed consideration of device pros and cons. For example;

> *'Just weighed good parts up and bad parts, stopping alive a bit longer, keeping working, obviously bad parts is dying isn't it'* S6

> *'I couldn't think of many disadvantages really other than having something stuck in your chest and knowing that in so many years' time it might have to be replaced'* C21

Once the decision to accept had been made the logistical planning for surgery was also a consideration for some. Having reconciled themselves to the sudden realisation of clinical need they then found themselves on a 'waiting for death' list;

> *'I think worst part is, is like waiting to go'* S6

> *'I had a 4 or 6 week wait I'm not sure exactly how many weeks between OK there's the decision we'll go for it to when I actually had the surgery because*

> *then you are counting down the days until that risk is taken off, that weight is taken off your shoulders'* and *'That six week window you know, once I mentioned you know you don't want the hideous irony of dying'* L11

> *'You know you think to yourself is my condition that bad, if it's that bad now why has it taken so long'* W12

Participants were asked to elaborate on their understanding of perceived benefits and harms. The immediate four week driving ban and on-going driving related worries were immensely problematic for all the drivers regardless of acceptance or not;

> *'Yes, a month and that was absolutely a pain in the back side because we live in the country, so yeah that was a real pain for a month'* L11

> *'For me driving is a big big thing and I do it and that's what concerned me, one what if it goes off when I'm driving'* S35

The invasive nature of the device was also a concern for many. Half the interviewees were surprised by the device size;

> *'I was a bit surprised about the size of it, I expected something sort of like, you know like, I don't know like a large watch battery size'* W12

C21 observed;

> *'She's got a tin full of these things and she pulls out a little one and says that's that and then they got bigger and bigger and then she said and that's what you're having because they are quite a bit bigger aren't they'* C21

The subcutaneous device (S-ICD) offers more limited therapy and is bigger than the trans-venous system, but it eliminates the potential complications associated with trans-venous access. This was a preferable option for some;

> '*There was quite a big tipping point between the subcutaneous option and the trans-venous option. The much more benign option of a subcutaneous ICD sort of, was almost a stroke solving'* L11

There was a mixed response when asked what they knew and how they felt about shock therapy. Those who accepted the device, generally either accepted shock therapy as a fact, did not appear to consider it or were not unduly worried by the thought of it;

> *'That's not a problem to me I don't want it to go off, I don't even especially think about it going off actually'* C17

The potential to receive a shock while driving or in a highly public place was an obvious concern. Ultimately, the perceived threat of early death and greater desire to prolong life prompted a risk averse decision and preparedness to submit to the ‘safety’ of technology, regardless of the consequences;

> *‘It’ll keep me alive, that’s the main thing'* S6
>
> *'The potential to live longer to be honest with you, if I can’t go running around then well that’s fair enough but at least I’ll be seeing tomorrow morning'* W12

Though it was not a case of life at any cost for all;

> ‘*It’s not life at any cost for me'* and ‘*I want to enjoy life I don’t care about how long I live especially, it has to be the quality*' C17

Other limitations on activities of daily living whether driving related or not, such as work, swimming or socialising was not as concerning for this group. In contrast, those who declined were more sceptical.

5.3.1.3.2 Prioritising Quality Over Quantity Of Life

Reluctance to live with, and unwanted reliance upon technology has been described in the literature and in this study applied particularly to those who hesitated or declined therapy;

> *'If I’m gonna die I’m gonna die I don’t want foreign bodies in me, inside me'* L9
>
> *'Taken aback that we were now talking about something that seemed to me to be quite intrusive and quite a sort of an almost disproportionate response to obviously what I had felt to be quite a minor thing'* and *'I had even got a few concerns about just the Reveal device'* L26

Device refusal was based upon the perceived negative impact upon QOL. They considered their personal risk to be minimal and the potential life-long harms to be unnecessary burdens, preferring to maintain self-control over their fate. They did not espouse faith in technology or the device and were more likely to contemplate the device specific harms. Regardless of the level of risk, whether it be 5% or 60% of having a SCA, L9 would rather die suddenly than face shock therapy, and would decline the benefit of cardiac resynchronisation, if it could not be offered without the defibrillator option. The fear of shock therapy, anticipatory anxiety and especially the negative impact of driving restrictions upon quality of life (QOL) outweighed the perceived benefit of a defibrillator for L9;

> *‘I sat and thought about it and just thought about it and I churned it over and I churned it over and. If you want to sit there and be a veg fair enough you can do it that way but I don’t want to be frightened of doing anything'* and '*If I have the defibrillator I can’t drive and it took me years to pass my test and I absolutely*

> *adore driving and I thought you know I can't live without, I couldn't not just get in the car and go every time it goes off'* L9

Similarly, L22 recollected;

> '*The main benefit is psychological kind of like piece of mind, if worse-case scenario happens you are protected but actually you know, he pointed out that some people who have them implanted have the opposite psychological impact, that they are worrying that they are going to go off'* L22

The perceived low clinical need appeared to sway the participants who declined a device, to consider the device harms to be greater than the gains;

> *'Infection risks always a big one, they talked about the technology itself and that I remember thinking Oh umm that what you are dealing with is a device that makes its own judgment about when it needs to do things and that inevitably must mean that occasionally that may misinterpret what is happening and act in a way that doesn't help you'* and *'The potential complexities and risks associated with it don't seem to be warranted given how my heart appears to be performing now'* L26

Despite severe symptoms and acknowledging the potential risk of SCA, those who declined remained unconvinced;

> *'There was another time when it looked like I'd had an episode of VT so these were two relatively minor incidents'* and '*Are we sort of bringing out sort of the big guns to fight something that might not need that'* L26

Likewise, having had episodes of diagnosed VT, and the fact that ICD implantation was discussed at every consultation, L22 still denied a significant risk of SCA and words such as '*threat*' and '*a joke'* were used to describe the recommendation;

> *'I'm making my decision based on the fact of like do I or do not need it because if I need it then the complications and the annoyances of having to get checked up regularly, it doesn't matter because that's not actually going to factor in, it's only factoring in at the moment because it's so, to me weak, if I need it I'll get it done it doesn't matter if it's going to be uncomfortable or annoying or whatever I'd have it done. In terms of my symptoms and how I feel you know I'm doing fine'* and *'How I'm viewing an ICD is that the longer you have it the more risk of complications therefore you don't want to have it until you really need it'* L22

Thus, the desire to live longer and potential to avert sudden death was associated with device acceptance, whereas when quality of life was prioritised, a definitive decision to decline was reached.

5.3.1.3.3 Tipping The Balance Of Benefit And Harm

One participant who hesitated for longer and reconsidered the decision, initially considered the risk of SCA to be too uncertain to warrant the invasive nature of a device and so placed greater emphasis upon the perceived undesirable factors. The anticipatory fear associated with shock therapy and potential limitation on quality of life was associated with hesitation and refusal. There was evidence of weighing up the '*insurance policy'* versus potential short and long-term complications;

> *'Once you open this can of worms, it's a lifelong can of worms'* and *'It was in the balance'* L11

For the other acceptors, device acceptance was generally based upon preventing an early SCD with no evident consideration of the fact that it could alter the manner of their death. Whereas, this was an important consideration for one participant who re-considered the decision;

> '*One of the considerations about an ICD before I had it was the way that that will change the death that I have because popping off very quietly, because sudden cardiac arrest is actually a nice way to go'* and '*It is a factor that I've thought about instead of having a nice quiet death probably whatever happens now I'm going to have a death which is repeated belts in the chest'* L11

For the other participant who reconsidered, the severity of symptoms and an open to suggestion attitude prompted initial device acceptance until the potential negative impact of shock therapy upon driving freedom was realised, forcing a change of mind. The implications of CRMD for driving, work, social activities and quality of life was an important indicator in declining a device;

> '*I said to my wife I'm not going to have it fitted you know, if I have a heart attack I have a heart attack but frankly I can't cope with the consequences of all that you know'* and *'It just wasn't, it wasn't a tolerable thing for me'* L34

The tipping point in favour of device acceptance was an increased perception of the risk of SCA which eventually overwhelmed their concerns. For instance, an unequivocal VT diagnosis and increasing appreciation of clinical need, coupled with positive reinforcement by the experts was enough to negate initial doubt;

> *'All of a sudden this is front and centre, you are going to have an invasive treatment and it's about your risk of sudden cardiac death and not about other stuff which is I guess about confronting. You have the realisation that it actually applies to you and you talk about the risk of sudden cardiac death'* and *'In terms of accepting, going for the defib it was removing the cloud, the risk'* and *'In my head I've stopped being inhibited by the risk of having a cardiac arrest'* L11

And the persuasive provocation of an increasing recognition of SCA risk provided impetus to swing the balance back in favour of device acceptance;

> *'The clinching thing was nurse said look if you had one of these ventricular arrhythmia or whatever nurse said it will almost certainly kill you, it's a Hobson's choice, you know nurse said you are damned if you do or damned if you don't so quite frankly you might as well accept the living option and accept the six months* (driving ban) *if it goes off as accept the death option. Nurse said there isn't a positive outcome from this if that happens to you, except one way you live and the other way you probably don't'* L34

Thus, having made an impulsive decision, reshaping perception of need was instrumental in the final acceptance. A re-evaluation of personal risk of SCA, symptom severity, the strength of recommendation and/or undesirable consequences could influence the ultimate decision. In this study, personal goals in terms of quantity and quality of life were a particularly powerful influence for the participants and their decision to accept or decline. Thus, 'planning the journey' represents a finely balanced consideration of the personal priorities, perceived safety and risks, benefits and harms associated with the chosen path.

5.3.1.4 Travel Agency

'Travel agency' refers to the perceived level of collective participation with others in decision-making. In this study, most (17) participants expressed the view that they had personally accepted responsibility for the ultimate decision.

5.3.1.4.1 Passive Or Active Decision-making

Within the group who readily accepted the expert's recommendation as the best option without further consideration, complete passive deferral to the HCP for final decision-making was generally implicit rather than explicit;

> *'Well he decided to put me name down'* L2.

> *'I wasn't pushed, I was you know, advised* (emphasised) *if you like in a very pleasant way'* W15

> *'It was Dr X that offered it to me but it was my decision to accept or reject, there were no pressure either way'* W20

Although this participant (W20) also denied reading any literature given, and his decision was made solely upon a brief bedside conversation.

Those who were either pre-prepared or took time to deliberate the recommendation and gather information, appeared to be more in control of the decision, though it was not in any case independent of the expert's advice. Generally, there was a sense of the 'ball's in your court' throughout the interviews, whereby patients received information from the experts and booklets and were then encouraged to make a choice that could be described as 'active informed' rather than 'active autonomous' decision-making;

> *'I absolutely feel that I was allowed to make the decision, I was given all the support that I needed to help me make the decision'* L11

Several participants described being presented with the information to support their decision;

> '*She gave me all the opportunity to say no I don't want it doing or what have you or I want some more information, all that you know was there if, I just needed to say yes'* and *'At the end of the day the decision was mine you know, they can only make their recommendations can't they and it's your choice whether you want to act on those recommendations or not'* W12

> *'It's very much down to like here's the information and I'm going to present it in a way that I hope you will take seriously or whatever but it's kind of up to you'* L22

> *'I think probably myself. I just decided. You know my husband just said are you going to have it done and I said you know I think so'* S44

5.3.1.4.2 Collaborative Participation

Shared decision-making (SDM) is thought to promote a balanced process of decision-making. In this study, only three interviewees suggested an element of shared responsibility for decision-making (SDM);

> *'It was Consultant and myself. I think between us we came to the conclusion that it would be beneficial'* L3

> *'I mean ICD Nurse didn't make the decision for me but he gave me the facts and discussed in depth and I was even more sure that I wanted to go ahead with ICD and pacemaker'* L4

However, a collaborative approach was not evident especially in L3's transcript. When asked who they felt was the most instrumental in their decision-making, most participants stated the doctors and / or specialist nurse.

Sixteen participants acknowledged being influenced in some way by the family. Generally, this amounted to discussion with their next of kin. Family commitments and a desire to live longer for the family was considered important. The decision for three of the men was largely dictated by their spouse whereas the female participants did not rely upon the advice of their spouse. Having family members present during consultations was clearly valued and acknowledged as helpful in terms of understanding and remembering the information by several patients. Three participants considered themselves to be the most influential in their decision-making.

5.3.1.5 Endorsing The Decision

What became apparent was the meaning of device therapy in terms of coping with their own mortality. While participants frequently referred to the inevitable fate of death, it became apparent that the distinction between acceptors and decliners revolved around the meaning of device therapy, in terms of facing their own mortality and the security *or* stress associated with CRMD.

5.3.1.5.1 Security Or Stressor

Those who acquiesced to the device acknowledged the threat of an early death and were content to accept any opportunity to mediate that risk. They were prepared to face the constant reminder of their own mortality and accept the additional protection and security the device provides. This in turn served to reduce the perceived threat from SCD. Those who did not hesitate used terms such as ‘optimist’ to illustrate their positive outlook;

> *'I always see the optimistic side of every situation and every set of circumstances'* W15

> *‘I'm always forever the optimist, my glass is always half full sort of thing you know so I have a bit of a heart problem but as long as I take it easy and steady I should be alright you know and not over do it'* L28

There was a tendency to display a matter of fact attitude and convey a more positive than negative message among those who accepted the device;

> *'You've got something that in the event it was to work, good. In the event it wasn't to work, tough s**t but at least you've got it if it was to work yeah so leave it at that kind of situation'* L2

> *'I don't want it to go off, I don't even especially think about it going off actually and if it never goes off then fine and dandy and if it does, it does and I'm not worried about it I'm pleased about it'* C17

Several acceptors described the decision as a '*no brainer'* based upon device capacity to provide '*additional protection'* and prolong life. They also communicated a desire for extra vigilance or '*monitoring*' variously describing the device in terms of a *'security blanket'*, *safety net'*, *'reassurance*', '*back up', 'insurance policy'* and '*peace of mind'*. Terms such as the '*Rolls Royce version'*, '*all singing all dancing'*, '*piece of magic'* and *'having a paramedic inside you'* described their belief in the device. Analogies were often used to explain their view, referring especially to cars, spare engines, a new starter motor, MOT's and 'tune ups';

> *'It's like being in the AA, your car might never break down but at least you've got cover in the AA if you do breakdown. It shows you that bit more peace of mind yeah'* L2
>
> *'I think my God if something does happen at least I'm not on my own even if I've got my machine'* W20

Regardless of device type (CRT-P/D or ICD), for those who accepted a device, the desire for symptom relief in addition to its life saving capacity strengthened their resolve to accept the device.

> *'If you don't have it done you'll stay as you are, could possibly get worse she says at least it'll improve your breathing. She says so you know the long-term benefits will be a lot better. At least if you've got your defibrillator and you do go in to cardiac arrest at least it'll keep you alive'* W18

ICD recipients also recognised the potential for advanced pharmacological treatment or bradycardia pacing to improve their symptoms;

> *'They might be able to do something with the drugs that I was currently getting, increase to give me I think a better way of life'* L27

In contrast, those who deliberated for longer or refused, considered the device to be an undesirable, constant and frightening reminder of their own mortality which they were less willing to confront. Rather than security, the device represented a stressor which served to increase the perceived threat of SCA. To legitimise their thinking, they appeared to manipulate and minimise their perception of need and convince themselves that it was not necessary. Denial and avoidance were more evident among this group. They admitted to *'parking'* the possibility of a serious cardiac condition, for example L11 said;

> *'It had been factored in to my thinking but still parked at a distance which kept it comfortable'* L11

L22 admitted believing that the risk was very small and difficult to quantify. She felt able to put that very small risk into a box;

> *'Problem with ARVC for me is you can't live thinking I'm at risk of a cardiac arrest because it would drive you bonkers and you couldn't live like that and so it's almost a coping device is just to forget about it, it's beneficial not to have that in your mind, sort of programming yourself not to think about it'* and *'It's that thing of like, you've opened that box again of it's a risk, Oh my God 10% again a minute without CPR'* L22

Furthermore, unlike the unmindful activity of a CRT pacemaker maintaining a normal rhythm, the threat of shock therapy was considered too extreme and 'shocking' to accept. L9 talked about fear and avoidance;

> *'If I'm frightened of something I won't do it'* and *'I knew if I get an electric shock I'm scared to death and I won't go near the damn thing'* L9
>
> *'All anybody there* (CMA UK) *obviously wants to know is when did your ICD last go off'* L22

There was a sense that, getting on with life and sudden death when the time comes, was preferable to the constant reminder of death;

> *'If my hearts gonna pack in I'd sooner it just do it than not shock me and give me warnings every time it's decided to stop Oh it's just stopped, bang whallop I just don't want that if I'm gonna die I just want to do it without knowing about it'* and *'If it happens it happens, if it doesn't it doesn't and that's it'* L9
>
> *'I just thought well if I just have the pacemaker put in and I don't have a defib am I gonna, what happens if the heart does stop. Well I thought well it's gonna stop anyway sooner or later, you know so there's nothing really to it. So as long as I am getting satisfactory out of life up until something does happen well'* L9

An element of medical technophobia also appeared to enhance the reluctance to accept a device;

> *'My natural disinclination towards extreme medical interventions played a major role in my decision too'* L26

For those who hesitated, it was only when the threat of SCA became overwhelming, and an unequivocal diagnosis of VT, that they could 'unbox' and confront their fears and the need for device therapy. Thus, for those who declined, continued deliberation may eventually reshape perception of need for CRMD in the future;

> *'If my cardiologist said to me look you know here's data that is showing you know progression or came out with data or statistics like hard data and hard statistics, then obviously I would then really re-think. It's a tricky one'* L22

This suggests that disease progression as an indication of increased risk of SCA may provide a categorical and more persuasive need for device implant.

5.3.1.5.2 Optimism Bias And Taking Control

Several participants appeared to vindicate their decision with the belief that the risk of requiring or receiving shock therapy was low. For example, L4 refers to her low risk several times;

> *'Everybody's made it very clear that I am low risk. I did think it is a bit of an over-reaction because you know I thought it only is a low risk'* L4
>
> *'I think it's 1 in 5 or 2 in 10. He says I might hopefully never have to use it so'* S6
>
> *'The chances are of it going off she says are slim'* W12

Furthermore, some participants believed that they may not be aware of shock therapy;

> *'You may not even notice that it's gone off, that it's done it, we will notice and we will let you know that that's happened, I believe that's right and what they said'* W15
>
> *'I'm sure I was speaking to someone who said and sometimes you get a shock and you don't even know you've had one'* L27

The low perception of likelihood of requiring shock therapy may also reflect a focus upon symptom relief rather than life prolongation for some.

Some participants, particularly the more hesitant and those who declined, appeared to adopt a more problem-solving approach, to take control of the situation. They described adopting various strategies to *'manage their own condition',* '*manage own health*' to minimise their SCA risk, such as medication reliance and compliance, ablation, keeping fit and modifying their lifestyles;

> *'I don't smoke and I'm not a person who sits around doing nothing'* L9
>
> *'I've always kept myself fit, tried to minimise my controllable part of the risks'* L11

> *'I'm keeping fit but also having modified my lifestyle in terms of I don't do strenuous exercise, luckily I've never done any illicit drugs and I think the third one he said was to avoid high levels of emotional stress. I have made modifications in terms of the work that I do and what I try and fit in to a day'* L22
>
> *'Given the fact that, you know I am on a whole lot of medications which I think further provide me a buffer of protection'* L26

Finally, some participants who ultimately accepted the device described CRMD in the context of worse possible scenario, working back from the threat of transplant and open-heart surgery, presenting device therapy as a preferable option.

5.3.2 Information Exchange And Recall

The second Strand 2 aim was to explore the level of information exchanges and the impact upon patient knowledge and understanding. Participants were asked what, where, when and from whom did they gather information. The patient narrative largely revolved around their recall and perception of the consultations and their knowledge and understanding of the condition and CRMD. Two main themes emerged from the interviews (Figure 5.7).

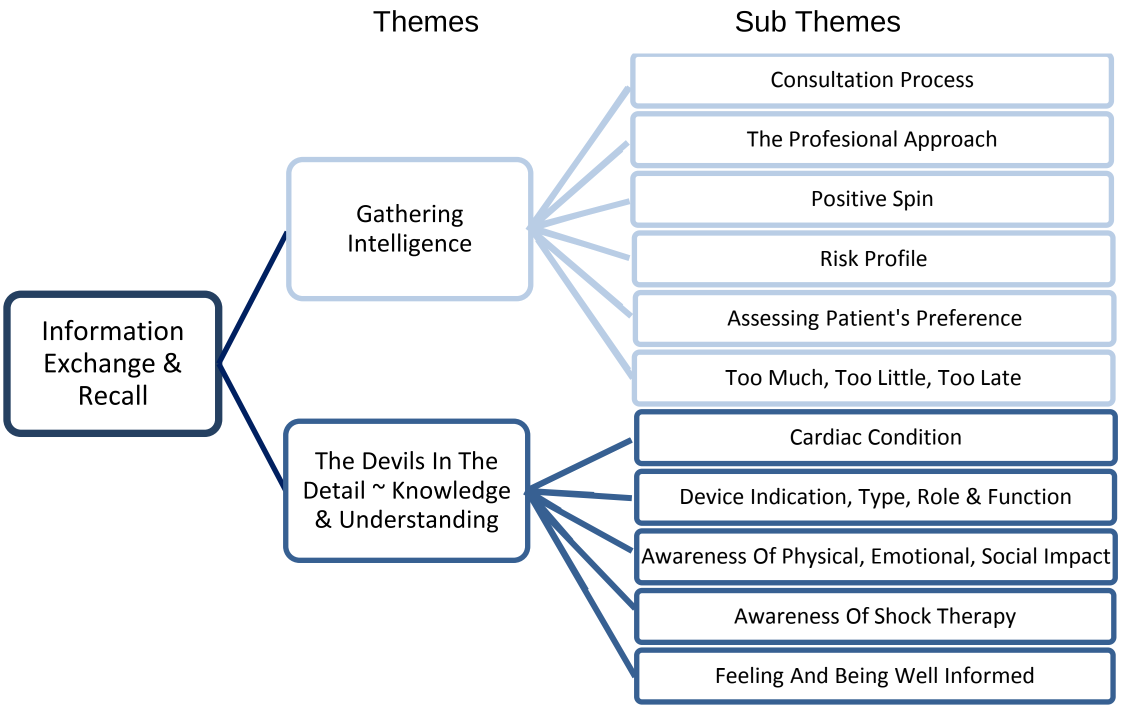


Figure 5-7 Information Exchange And Recall Framework

5.3.2.1 Gathering Intelligence

‘Gathering intelligence’ is concerned with the nature of the patient-professional interaction and whether this influenced knowledge, understanding and device acceptance or rejection. The healthcare professional’s approach to information giving appeared to be an important influencing factor for some participants.

5.3.2.1.1 The Consultation Process

Initial exposure to information came from the recommending consultant. Interviewees were recruited from four implant sites and were under the care of several different consultants within each site. The three patients who declined a device were all from the same site. Adherence to current NICE guidance for device recommendation (NICE, 2014) was confirmed during the preparatory observation of clinic conversations between potential device recipients, doctor and an ICD nurse specialist, and was referred to by some interviewees. The field notes from one clinic observation can be found in the supplementary information[3]. Ideally, following initial recommendation and provision of a generic, information booklet from the consultant, patients should be referred to a specialist nurse or physiologist for a more detailed discussion. Slight variance in the consultation process was observed across and within sites. Fourteen patients were offered the opportunity to see a nurse specialist. Further enquiry concluded that 11 of them were very well informed. However, the other six participants only saw the consultant pre-implant. This was due to non-referral (n=2), seeing the nurse on the day of implant (n=2) or missed phone call opportunities (n=2). A greater proportion of those who only saw the consultant appeared to be less well informed than those who saw both, suggesting that patient-professional interaction and repetition does influence information uptake and recall (Figure 5.8).

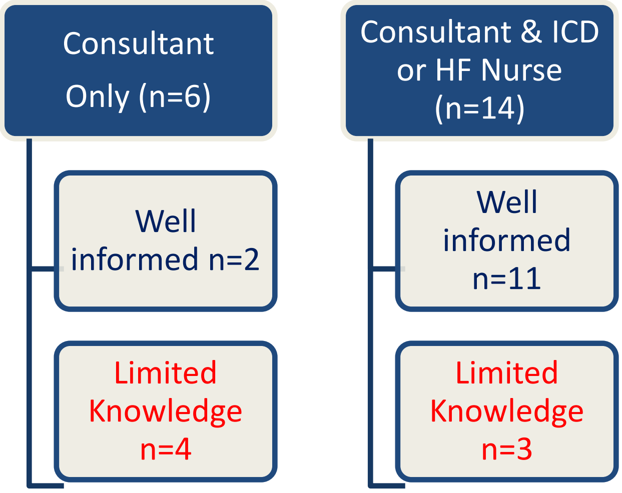


Figure 5-8 The Consultation Process

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[3] The field notes are available in the supplementary information.

5.3.2.1.2 The Professional Approach

The structure of information giving frequently prompted comment. ‘*Clear*’ ‘*thorough*’ ‘*logical*’ ‘*organised*’ and ‘*lengthy*’ were adjectives regularly used to describe the mode of explanatory information giving by the healthcare professionals. The length of time devoted to the discussion was equated with thoroughness;

> *'The anaesthetist took a lot of time and trouble, it was actually brilliant'* L11
>
> *‘She booked was it an hour slot or an hour and a half slot so you didn’t feel rushed did you. You were under no pressure'* C21

Furthermore, the amount of repetition by multiple information givers appeared to be of value;

> *'It was given to me very clearly. He thought it was very very important that I go and speak to ICD Nurse. He went through things, I mean I was absolutely amazed how much detail he went into, how much time, I mean we were there an hour I think and you know how thorough he was'* L4
>
> *‘She went through all, when they told me that I’d need a defibrillator there were a lady there that I saw straight after the consultation and she went through things, I think it was a nurse and she made everything clear’* W12

The *‘direct’* way in which information was given appealed to some patients. Words such as ‘*frank*’ ‘*blunt*’ and ‘*matter of fact*’ were used to describe a ‘straight John Bull’ approach;

> *'Basically, I was told, not in an abrupt way but very down to earth way, it wasn’t nasty or wrong it was, if anything it suited how I am OK straight facts and then that’s it you can make a decision based on that’* L2
>
> *‘I quite liked it because she was quite frank and open and no wishy washy, this is what it is, you need to know these facts because you need to make a decision, for me that is perfect, I don’t want it glossed over’* S35

Whereas, the ‘blunt’ approach did not suit all;

> *‘They’re less human shall we say than ICD Nurse’s approach, not saying that his approach was wrong you know but I can see that he yeah was matter of fact and you know and err a bit more personable with ICD Nurse* L27

To clarify the interviewer asked, ‘did you feel that you gleaned more from the personable approach?’ to which L27 replied in the affirmative. Others described it as ‘*open*’ ‘*pleasant*’ and ‘*thorough*’ which was interpreted to mean an ‘approachable’ style

> *‘So it was a relaxed atmosphere which helped me to relax'* L3

> *'She said in a very pleasant way, so for me not to panic, she explained it very thoroughly I thought'* W15

Participants specifically referred to language used and appreciated the use of non-technical jargon;

> *'She said it in laymen's terms you know what I mean she didn't go around corners she just told us it as it was you know'* W18

5.3.2.1.3 A Positive Spin

Tversky and Kahneman (1981) described the concept of 'framing' whereby people respond differently dependent upon the manner with which options are presented. Options framed in a positive way are more likely to induce risk averse responses, such as opting for the 'sure gain' CRMD recommendation. Options framed in a more negative manner, are more likely to provoke greater risk taking rather than opt for the recommendation. The effect of 'framing' is particularly relevant in healthcare decision-making, as the way in which treatment information is presented has been found to influence the patient towards the decision preferred by the physician, a phenomenon described as the 'framing effect' (Mikels et al., 2013). Evidence of 'framing effects' permeated the interviews, as most of the participants described receiving positive information. Device therapy was specifically portrayed in terms of life saving (ICD) and/or life improving (CRT) 'benefit' or focused upon beneficial outcomes with little or no emphasis upon potential associated harms for sixteen participants;

> *'She said you know you will definitely benefit from it'* and *'She said, if you don't have it done you'll stay as you are, could possibly get worse, she says at least it'll improve your breathing, it'll improve your oh I don't know your blood flow and stuff like that. If you've got your defibrillator and you do go in to cardiac arrest at least it'll keep you alive'* W18

The extract from L28 demonstrates the potential influence of benefit bias;

> *'When I walked out after talking to him you know you think, it doesn't sound too bad it's you know and if it's going to do me some good it's got to be good sort of thing'* and *'Yeah if it'll do me some good I'll just go with it like you know. Everybody's information was saying it's good, have it done it sort of backed up my early decision to have done. Everything was positive'* L28

An association between benefit bias and acceptance was notable among participants. This not only involved those who took the leap of faith but also the active information seekers despite them being more critical in their judgement. This has important implications for the way information is communicated to decision makers. L26 observed;

> *'It does speak for the power that they have got because they can influence massively someone's decision with the language they use, the seriousness with which they approach it'*

5.3.2.1.4 Risk Profiles

Providing a risk profile for SCA for different disorders, especially inherited conditions is particularly challenging. Participants were asked whether the consultant had offered any specific information regarding their personal risk of SCA. Online SCA risk assessment tools for inherited disorders are available and were introduced to some participants with HCM / ARVC during the consultation with the consultant or ICD nurse. Others were given an approximation of risk, otherwise risk profiles were not discussed. Participants were asked, whether they found it useful and if not whether they would have appreciated it. There was a general lack of desire for, and belief that statistical information related to personal risk of SCA, device complications and shock therapy would have helped their decision-making.

5.3.2.1.5 Assessing Patient's Preference

Within the individual interviews, there was no evidence of assessment of levels of patient knowledge and understanding, though this was not the focus of a specific interview question. However, participants were asked whether HCP's attempted to elucidate their personal goals and preference. Some did recall being asked about their values, beliefs and opinion, for example;

> *'Before they did anything sort of thing I suppose so that I could say no I don't I've changed my mind. She arranged for me to have it done if I wanted to go ahead'* S44

However, it was not always clear how enabled patients were in articulating their personal view;

> *'Well yes I was given that option of what I want to do which like I says once they'd spoke to the other doctors and one said to me it'll stop you dying, imminent death, well I think that kind of thrown everything, whatever I was thinking about got thrown to one side'* L2

> *'We talked about it a little bit and he said "how do you feel about it?" and I said yes I think it can only be good, you know from the information that I have' L3*

> *'Heart nurse asked me what I thought'*. 'And what did you say?' (interviewer) '*I don't know'* S6

Most participants could not recall being asked outright what they wanted to do;

> *'They've never, it's interesting I don't think I've ever, I've never been faced with a do you or do you not want this kind of thing'* L22

That said, those who declined acknowledged that their reluctance to accept had been recognised;

> *'I think my cardiologist here clocked me as you know not sounding keen and he said well why don't you speak to the specialist arrhythmia nurse here because they know more about it'* L22

> *'If you ask Dr at the end of that meeting umm is (L26) going for this he would have probably said no it doesn't sound like he is*' L26

Despite having made a rapid decision, most recipients and all decliners described being given time to deliberate;

> '*'Dr X was leaving it very much, you know he was letting me think about it'* and *'I mean it was done in an excellent way, it was discussed and thought about for about a year before we went ahead with it'* L4

> *'I came away and she phoned me to say yes they want that but gave me time to think whether I needed it or not'* S35

> *'It does give you time, thinking time and time to have a little look around and talk to a few people'* L34

5.3.2.1.6 Too Much, Too Little, Too Late

Some participants admitted to receiving too much or too little information or having difficulties understanding or recalling what they had been told;

> *'I was dealing with some many different doctors, ICD Nurse and other fellow about this giving me all the information I needed and obviously they've given me information which has gone over your head, which hadn't registered in'* and *'If anything, I've been given too much information right*' L2

S44 felt confused when she was told too much at one time. The importance of adequate time and information at first recommendation became apparent by its very absence;

> *'I really shuddered out of horror I've got to say I was staggered that the consultant hadn't mentioned anything because it's a complete life changer for me, I read this and I couldn't believe it that he actually never said anything'* L34

This was further emphasised by the number of relevant questions posed by some recipients during the interview, suggesting that they had not been fully informed to make the decision or consent. It was however difficult to ascertain whether this may have been an issue with recall or a degree of selectivity in terms of information filtering;

> *'I will read the literature I've been given. That's another thing it's like a crystal ball isn't it. It's like a fortune teller you hear what you want to hear*' W15
>
> *'She just said there's a few side effects, she said what they were. I can't remember but she says I still think you'll benefit by it*' and '*I mean it's all in here and out of there but they know what they are on about so'* W18

5.3.2.2 The Devils In The Detail

The 'devils in the detail' describes the amount of knowledge and level of understanding recalled by participants during the interview. The aim was to determine whether patients had enough relevant information about their cardiac condition, device indication, role function, benefits and potential complications to reach a desired decision and provide informed consent. This was determined by assessing the amount and accuracy of detail provided in response to specific questions. Participants were prompted to elucidate the finer details of their knowledge recall. A colour coded matrix of knowledge recall by participant was developed[13]. There was a notable difference in the amount of information recalled and the accuracy of understanding between those who avoided further information and participants who systematically gathered additional information.

5.3.2.2.1 Cardiac Condition

Those who did not seek information beyond that received from the experts demonstrated a varied and often limited amount of knowledge. They were not well placed to explain their cardiac condition;

> *'I don't know whether it was a small heart attack or heart failure, I don't know what it was'* L3
>
> *'I'd had this ruptured artery and I'd ignored it and this was the coronary artery, I had a stent fitted'* L28

Conversely, the active information gatherers demonstrated evidence of knowledge and understanding of their cardiac condition;

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[13] Colour Coded Matrices Of Levels Of Knowledge And Recall are available in the supplementary information.

> *'All the coronary arteries in my condition are all normal there's nothing … it's basically the left ventricle stretches, dilates and because it is dilated it then isn't strong because it can't pump so that's basically what the condition is'* S35

5.3.2.2.2 Device Indication, Type, Role And Function

There was mixed insight of device indication, role and function among those who uncritically accepted the device;

> '*He said it would have this extra attachment which would jump in if my heart started to falter for any reason, I didn't ask anything about it I didn't realise, I thought it was part of the pacemaker but it's a separate piece'* L3
>
> '*It's got 2 wires it can differentiate between being out of breath walking up a hill or strenuous exercise as to a life-threatening heart rhythm'* L28

Whereas, the systematic information gatherers could largely reconcile their cardiac condition with the indication, type, role and function of the device;

> *'We had a look at the algorithm with the degree of heart failure and the left bundle branch and the degree of irregularity and ventricular pacing etc and mine was down there clearly requiring a defibrillator version' C17*
>
> *'They never said that this would cure the AF it was just a resynchronisation'* C21

5.3.2.2.3 Awareness Of Physical, Emotional And Social Impact

Those who took the leap of faith could not articulate some of the potential harms the device might incur;

> '*I think they did, although I can't remember what the potential risks were when I try to recount it'* L27

Others either could not recall information received, recounted inaccurate accounts or asked specific questions about shock therapy, deactivation, diaphragm pacing, battery change and other potential undesirable effects during the interviews. In contrast, the information seekers had investigated the potential impact of device therapy upon their daily life. Deactivation should be discussed pre-implant but rarely was. In addition, long term concerns related to battery replacement and lead problems seemed to occur to a few but not the others;

> *'I had more specific questions about the nature of risks, how do you remove batteries and the device after ten years and how do you replace them'* L26

> ‘*There is an issue with the leads and the leads do grow over a bit. That sounds problematic. Obviously infection risk is always a big one’* L26

Regardless of the level of information gathering, reference to the potential positive and negative effects upon emotional well-being was either not evident or not well articulated by over half of the interviewees. Those who expressed a view, generally conveyed realistic expectations of their device;

> *‘Nurse said it probably isn’t going to affect your day to day life or make you feel any better other than psychologically perhaps nurse said because you’ve got some reassurance’* L34 (ICD)
>
> *‘It won’t cure what I’ve got and it could deteriorate as life goes on, it’s not a cure’* S35 (CRT-D)
>
> *'Dr X did say to me that it was only for prophylactic it wasn’t, you know it was just there as a safeguard, it wouldn’t help my symptoms or anything’* S44 (ICD)

5.3.2.2.4 Awareness Of Shock Therapy

The participants who had avoided gathering additional information were not aware of the possible impact of shock therapy;

> *‘A defibrillator which jumps in when my heart beat gets a bit erratic, now if that jumps in would I feel it? because I’ve never felt it, a little punch?’* L3
>
> *‘From what would be a noticeable shock if it’s a biggey, that that machine has decided it’s going to be a biggey, they said you may not even notice that it’s gone off, that’s it’s done it’* W15

When asked whether he had looked in to shock therapy;

> ‘*No, no I haven't’* ‘Why not?’ (Interviewer) *‘Umm I think I’d be full of trepidation and waiting for this to happen and it’s not going to be nice, that’s my feeling at the moment of it. If I need to know I’ll be told’* L27

An awareness of shock therapy, potential procedural and post implant physical issues and the impact upon daily activities was evident among the information gatherers;

> *'I’m just conscious now that if the worst came to the worst and I did have something related to my myopathy that my death now would be something writhing around on the pavement with this thing frantically trying to keep me alive instead of me just going quietly but too young’* L11
>
> *‘I would perhaps get a little bit of a warning I might feel a bit strange and if I did just to sit down because they can knock you on the floor if you’re stood up, she*

> *said it'll be like a thump in your chest like someone's kicked you in the chest'* S44

5.3.2.2.5 Feeling And Being Well Informed

When asked, fourteen respondents stated that they felt well informed. For six participants, this appeared to translate into what might be regarded as an informed decision. Another six interviewees may not have been fully conversant with enough information as they made the initial, hasty decision, however subsequent systematic information gathering ensured that they appeared to be well informed at consent. For example, L9 refers to '*big words'* and '*gobbledegook*' used in the literature but actively seeks clarification and further information from the ICD specialist nurse. Whereas, regardless of whether they believed themselves to be well informed or not the eight 'leap of faith' device recipients did not appear to have given fully informed consent.

5.3.3 Summary Of Strand 2 Findings

In summary, with respect to the Strand 2 aims and objectives, this study revealed the following;

Aim 2: To develop a deeper understanding of the patient experience, explore how patients approach decision-making and generate themes about the decision-making processes employed.

To explore how patients, respond to the initial recommendation for primary prevention CRMD and determine whether it affects their engagement with decision-making;

- Personal appraisal of symptom severity was not necessarily associated with perceived clinical need
- Recommendation for primary prevention CRMD elicits an initial shock, fear and surprised response
- For some, the CRT was also associated with relief that it may improve their symptoms
- Most of the participants recommended for a defibrillator acknowledged their increased risk of SCA and an appreciation of clinical need. This was not so for one participant who declined a device
- Immediate or eventual acceptance was generally associated with a recognition of clinical need and perception of a strong recommendation. Those who declined remained unconvinced

- The initial response triggers an immediate, impulsive ‘yes’ or ‘no’ decision.

To investigate the extent to which CRMD patients engage in systematic and heuristic information gathering;

- Fast, heuristic thinking based upon immediate information received from the experts and personal experience or that of others was evident among all the participants
- Although expert opinion was important to all, the value placed upon expert opinion appeared to differ among the participants and may have influenced their approach to decision-making. Furthermore, it did not necessarily translate in to device acceptance
- Recall of positive personal experiences was associated with immediate device acceptance
- Participants who took more time to gather further information and deliberate over the decision were more likely to recall negative experiences
- Four types of decision-making emerged, determined by adoption of a decision approach distinguished by the degree to which they sought further information and the final decision reached
    i. One group of participants used various expressions to describe a ‘*leap of faith*’. ‘Leap of Faith’ was characterised by an uncritical acceptance of the immediate decision based solely upon expert opinion ± the opinion of significant others and / or informed by prior experience. These participants expressed no desire, made no effort or actively avoided information gathering beyond that received from the experts. Heuristic information processing dominates this group
    ii. ‘Reinforced Acceptance’ describes how some participants entered a period of systematic information gathering and deliberation to ‘*reinforce*’ the initial decision to accept the device
    iii. ‘Reinforced Refusal’ represents 3 participants who gathered further information to ‘*reinforce*’ their decision to decline a device. Heuristic and systematic information processing is evident
    iv. ‘Reconsideration’ describes a process whereby heuristic and systematic information gathering and deliberation, led 2 participants to ‘*reconsider*’ their opinion away from the initial decision.

To examine the extent of collaborative decision-making evident in current local practice;

- There was some evidence of paternalistic, passive decision-making among those who uncritically accepted expert opinion
- The systematic information gatherers appeared to have more control over the decision but not without serious consideration of expert opinion
- Otherwise, the perception that participatory decision-making was collaborative, active and informed prevailed
- Most (17) participants believed that they had personally accepted responsibility for the ultimate decision
- Either discussion with or consideration of family commitments influenced the decision for 16 participants
- Men were often directly influenced by spouse opinion. This was not the case for the female participants.

To determine what factors are perceived by the patient to influence the adopted decision approach, acceptance or refusal and decisional regret;

- The distinction between acceptors and decliners appeared to revolve around the meaning of device therapy in terms of facing their own mortality and the perception of CRMD in terms of additional security or stress
- The motivation for device acceptance and refusal was also influenced by the degree of importance attached to perceived benefits and harms
- The desire to live longer and potential to avert sudden death was associated with device acceptance
    i. Those who took the ‘leap of faith’ accepted the security of device therapy and life prolongation, over and above all else with little consideration of the possible harms
    ii. For some, ‘living with’ versus ‘dying without’ and / or ‘improving symptoms with’ versus ‘worsening symptoms without’ reinforced the decision to accept but not without consideration of the benefit and harms of device therapy
- The invasive nature and device size concerned many and the enforced 4 week driving ban and fear of potential loss of licence was problematic for most. The potential to receive shock therapy while driving was a concern
- When quality of life was prioritised, a definitive decision to decline was reached.
    i. The uncertainty of SCD, minimal perceived personal risk, unwanted reliance upon technology, potential device related complications, the stress of anticipatory fear of shock therapy and limitations on quality of

life outweighed the benefits for those who hesitated for longer, reconsidered and ultimately refused the device

- For those who were initially sceptical, an eventual realisation and acknowledgement of an increasing risk of SCA tipped the balance in favour of accepting a device
- Participants described different means of coming to terms with their decision. Some perceived the threat of device therapy to be low. Others focused more specifically, upon managing their own condition to minimise risk.

Aim 3: To examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent.

To discover whether the patient professional interaction influenced knowledge and understanding and device acceptance or rejection;

- A greater proportion of those who only saw the consultant appeared to be less well informed than those who saw the consultant and a nurse, suggesting that patient-professional interaction and repetition does influence information uptake and recall
- The healthcare professional approach was an important and persuasive aspect of the experience
- There was an element of benefit bias, however those who gathered further information balanced this with some knowledge of the potential risks and harms of CRMD
- There was a general lack of desire for, and belief that statistical information related to personal risk of SCA, device complications and shock therapy would have helped their decision-making
- There was a lack of evidence related to assessment of patient knowledge and preferences by health care professionals.

To identify whether patients have enough relevant information about their cardiac condition, device indication, role function, benefits and potential complications to reach a desired decision and provide informed consent;

- The majority admitted to making a quick, impulsive decision at the point of recommendation. For most this was not well informed
- Uncritical acceptance and consent for device therapy was not well informed

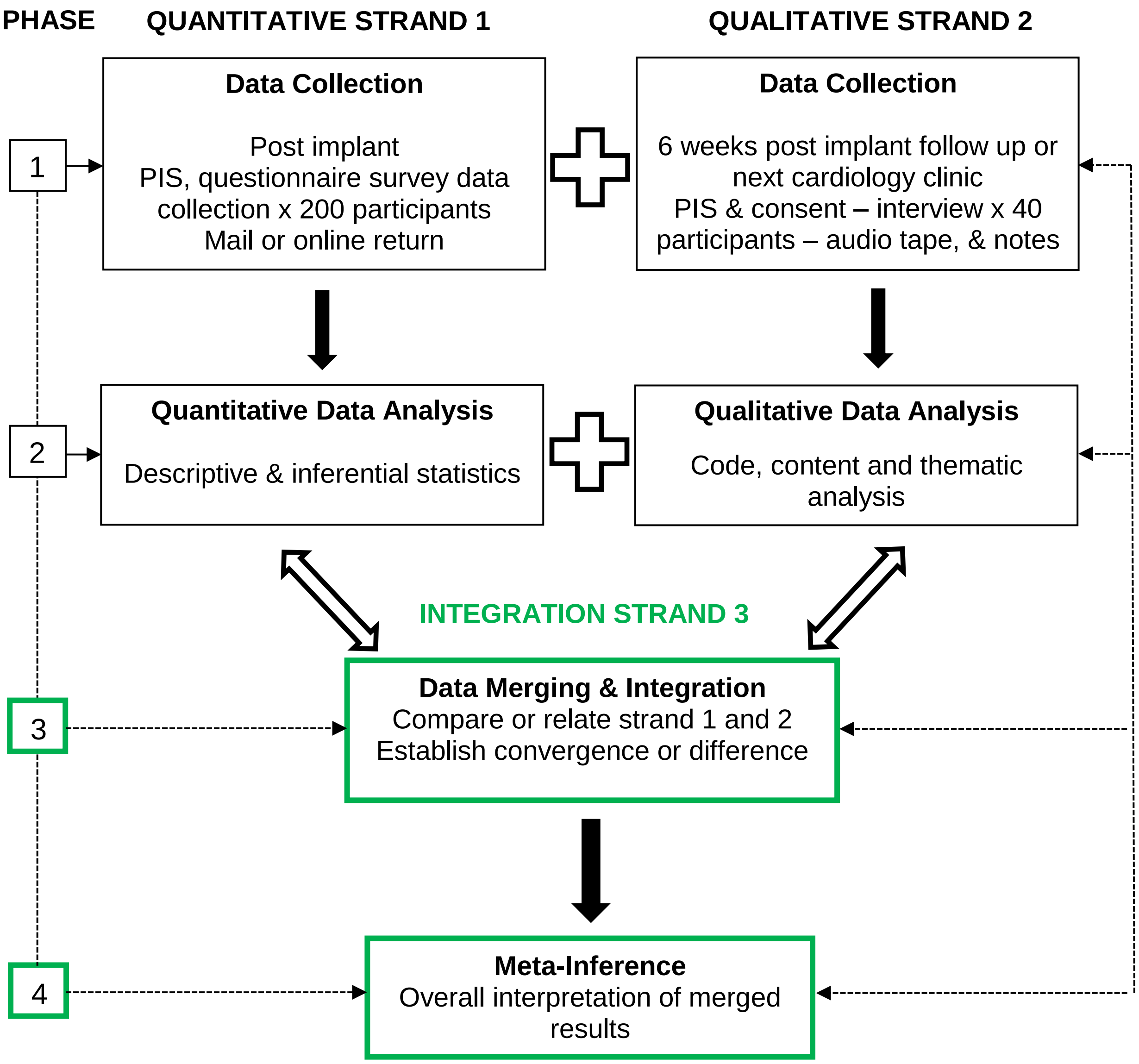
- Further information gathering, and thoughtful consideration resulted in greater evidence of a more informed consent
- Emotional concerns, deactivation and battery life were often not discussed
- Participants who avoided further information were not aware of the possible impact of shock therapy
- An awareness of shock therapy, potential procedural and post implant physical issues and the impact upon daily activities was evident among the information gatherers
- There appeared to be a discrepancy between feeling and being well informed among some participants.

Chapter 6 is concerned with phase 3, data merging and integration of this MM inquiry. It will provide the rationale and a detailed analysis of the Strand 1 and 2 data merging and integration employed. The development of the system of joint displays utilised to interpret the findings will be discussed and the findings are presented as a new theoretical model of patient decision-making for CRMD.

Chapter 6
Strand 3 Data Integration And Meta-Inference

6.1 Introduction

Phases 1 and 2, presented in chapters 4 and 5 respectively, involved concurrent, independent quantitative and qualitative data collection and analysis. The focus of Chapter 6 is phase 3 and 4 of this MMR study (Figure 6.1).



Key:
✚ denotes concurrence

⇔ denotes data mixing (Creswell, 2014; Creswell and Plano-Clark, 2011; Morse, 2003)

Figure 6-1 Concurrent Parallel, Convergent Mixed Methods Design – Strand 3

Phase 3 involves the integration of the findings from Strands 1 and 2 to form Strand 3. Phase 4 is the process of meta-inference, defined by Tashakkori and Teddlie (2008) as "*an overall conclusion, explanation or understanding developed through and integration of the inferences obtained from the qualitative and quantitative strands of a mixed method study"* p101.

Thus far, the criteria for exploring patient decision-making in the context of CRMD were generated from the scoping review, and applied to the development of a conceptual map based upon what was known about CRMD decision-making (Figure 6.2). For example, the HSM Framework described by Chen, S. and Chaiken (1999) and Charles et al. (1999) theory of collective participation. What was not known, formed the basis of the research question;

> **'What influences adult patients' decision-making in accepting or declining primary prevention complex cardiac rhythm management devices (CRMD)?'**

As such, the answer to the question relies upon theory based, deductive and real world, inductive reasoning. Therefore, a multi-phase, dual strand, parallel, concurrent, convergent mixed methods research (MMR) design (Figure 6.1), was selected as the most appropriate to answer the research question and aims (Creswell and Plano-Clark, 2011). Phases 1 and 2 involved the respective data collection and analysis for the Strand 1 quantitative (Ch.4) and Strand 2 qualitative (Ch. 5) aspects of this inquiry. Strand 1 was designed to deduce which and to what extent, elements of decision-making from the conceptual map could be applied to the CRMD decision-making participants in four implant centres in the UK. Strand 2 sought to generate new explanatory themes from the participants experience and inform the development of a typology of decision-making. The legitimacy for using themes in typological analysis depend upon their presence across all the participants in some form or another (Ayres and Knafl, 2012). This was demonstrated in Strand 1 and 2. In order for a typology to be of practical use, it must clearly identify the convergence of elements that distinguish one type of decision-making from another in an easily recognisable manner (Ayres and Knafl, 2012). Therefore, the purpose of data merging and integration in this study, was to confirm or refute the emerging typology of decision-making among these participants.

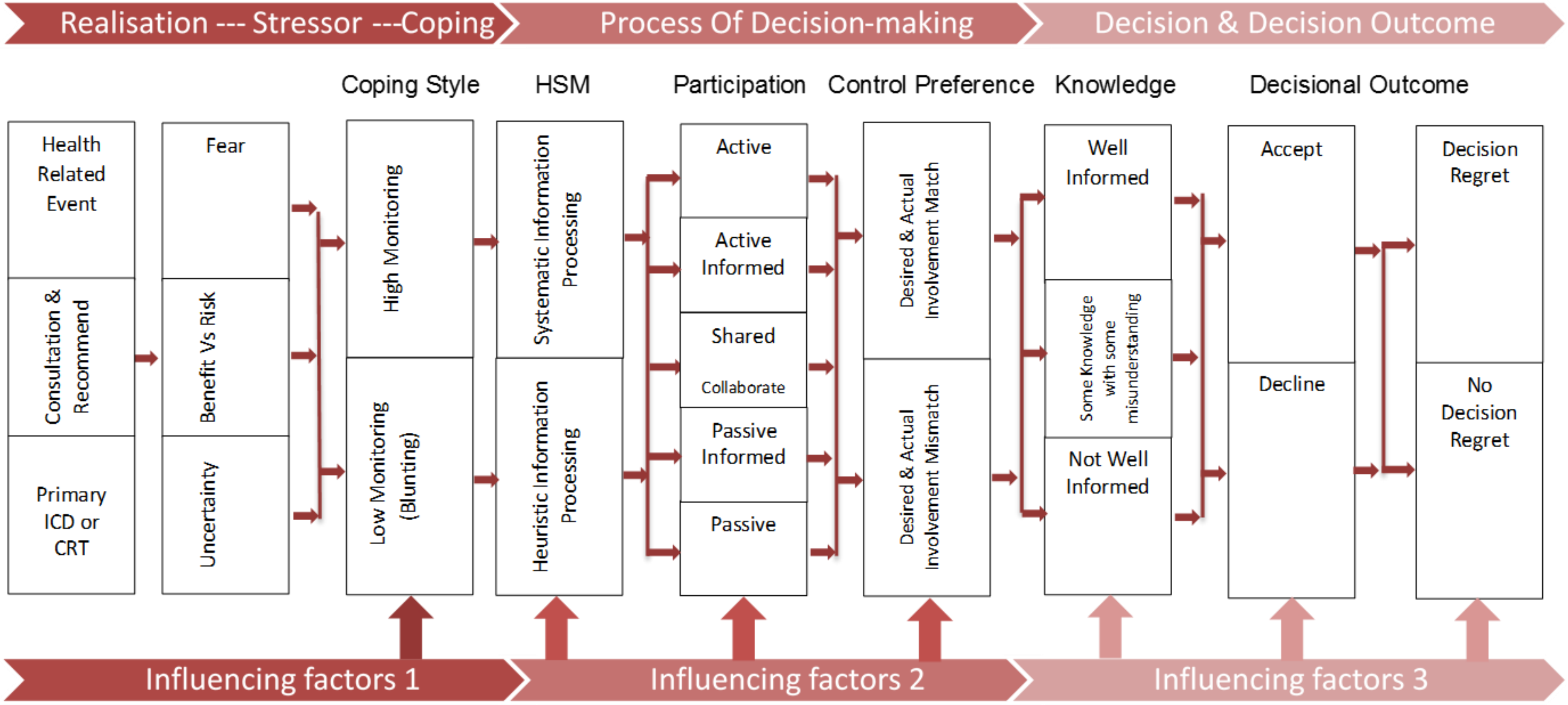


Figure 6-2 Conceptual Map Of Patient Decision-making Developed From The Scoping Review

The opportunity to optimise the quality of the study was also a major driver for data integration. Data integration can potentially offset some of the biases and weaknesses related to generalisability, validity, reliability and credibility inherent in quantitative and qualitative approaches (Creswell, 2015; Creswell and Plano-Clark, 2011; O'Cathain et al., 2008; Greene and Caracelli, 1997). In the study design, the merging and integration of findings from the distinct methods were planned, in order that conclusions may be applied to a wider audience. A summary of the main findings from Strand 1 and Strand 2 precedes a detailed discussion of the process and findings of Strand 3, data integration. The terms integration and merging are used interchangeably, as in the literature (Creswell and Plano-Clark, 2011). Finally in phase 4, the inferences drawn from the 3 Strands will be discussed.

6.1.1 Summary Of Findings From Strand 1 And 2

Strand 1 sought to establish whether an association existed between socio-demographic characteristics, situational context, self-reported coping style, adoption of a particular decision style, decision to accept or refuse CRMD therapy and decisional regret. Fifty, predominantly male (n=42), White British, Christian participants, aged from 34 to 82 years, living with or near next of kin, returned a complete questionnaire. Gender, ethnicity, religion, marital status and occupational status did not appear to influence decision-making. However, the homogeneity of this relatively small sample may have precluded discovery of a significant difference. NYHA as an assessment of symptom severity was not a factor. The CRT-P device was only implanted in older adults, otherwise device type was not significant.

The factors that did appear to significantly influence the decision-making approach and the decision made, among these participants were;

1. *Age*
2. *Cardiac condition – ischaemic versus non ischaemic aetiology*
3. *Aptitude for health literacy (HL) estimated by way of educational and occupational status*
4. *Coping style in terms of the level of monitoring*

There was a statistically significant association between age and cardiac condition, whereby older adults were more likely to have IHD, whereas younger adults were more likely to have a non-ischaemic diagnosis. Age was not significantly associated with HL, however older age and a lower estimated aptitude of HL were significantly associated with lower monitoring scores. Conversely, being younger and having a higher aptitude for HL were associated with a higher monitoring score. Furthermore, these factors appeared to influence and potentially predict the extent to which patients engaged with systematic information gathering and the ultimate decision. Being male was associated with a greater desire for active engagement, but gender was not a significant factor in actual participation. Age was not associated with the desired level of participation but younger adults were more likely to report actual active engagement. In addition, there was a weak correlation between lower monitoring scores and a reported preference for passive decision making, though this was not evident in the reported level of actual decisional control. Those who declined a device had a higher mean monitoring score than those who accepted. Reported decisional regret was minimal for most of the participants.

Strand 1 also aimed to identify the amount and source of information gathering and the degree to which patients could recall what had been discussed prior to the decision. Certain characteristics were associated with the extent to which participants sourced other information. Younger adults, high monitors and evidence of systematic information processing (greater variety of information sources) were associated with recall of a greater number of elements of information. In comparison, older adults, lower monitors and limited sourcing of other information was associated with a lesser recall of information.

Strand 2 was designed to develop a deeper understanding of the patient experience, explore how patients approach decision making and generate themes about the decision-making processes employed. It revealed insight into the thoughts and feelings associated with the presenting symptoms, the consultation and the recommendation. It revealed the nature of the subsequent decision-making journey, the perceived responsibility for the final decision and the factors that influenced the decision to accept or decline. Five themes and several sub-themes emerged to explain the patients decision-making journey;

1. *The recommendation* – the participants initial ‘shock’ response
2. *Mapping the landscape* – the immediate and subsequent fast and slow thought processes
3. *Planning the journey* – weighing up personal priorities and goals with benefits and risks of CRMD
4. *Travel agency* – the influence of others and collective participation
5. *Endorsing the decision* – rationalising the decision

Strand 2 also presented the opportunity to examine patient-professional interaction, the amount and direction of information exchange and explore the relationship between knowledge acquisition, recall, patient choices and informed consent in more detail. Two main themes and several sub-themes emerged;

1. *Gathering intelligence* – the patient-professional interaction
2. *Devils in the detail* – the amount and level of knowledge recall and understanding

Further elaboration on the personal experience of decision-making, revealed differences in the way participants reacted emotionally and physically to the recommendation. It provided greater insight into the extent of heuristic and systematic information processing, the patient-professional interaction and the level of knowledge and understanding acquired. As a consequence, 4 types of decision-making appeared to emerge, based upon the degree to which the participants had engaged with systematic information gathering, and whether the ultimate decision was to accept or decline a device. The terms used to differentiate the types of decision-making in Chapter 5 were;

1. *Leap Of Faith* – accepted the recommendation based solely upon expert advice
2. *Reinforced Acceptance* – sought further information to reinforce a decision to accept the device recommendation
3. *Reinforced Refusal* – sought further information to reinforce a decision to decline the device recommendation
4. *Reconsideration* – sought further information which served to extend the deliberative process, induce a change of mind and inform the final decision

The level of knowledge and understanding varied between the types of decision-making. Those who did engage in active information gathering were able to recall a greater number of elements of information exchange and relate their understanding of the issues with more accuracy and depth than those who did not.

The third phase of this MMR study was the mixed analysis of data from Strand 1 and 2, that is Strand 3. The principle intention of Strand 3 data merging and integration, was to determine whether the socio-demographic characteristics, monitoring behaviour, control preferences and decisional regret correlated with the type of decision-making, and so confirm or refute the emerging typologies of decision-making among this group of participants.

6.2 Phase 3 Data Integration

The quality of MM studies have been criticised for the absence of attempts to integrate data and findings from the different components within the study (O'Cathain et al., 2008). The process of meaningful integration of quantitative and qualitative data sets is still in its infancy and remains a subject of continued discussion and development (Guetterman et al., 2015). Several strategies of integration such as narrative description, data transformation and joint displays have been described (Fetters et al., 2013; Bazeley, 2012). Narrative description of the findings from both quantitative and qualitative data sets in the discussion is a common approach, however the extent of actual merging may be limited. Others have embedded one approach within the other though this can result in priority being given to one method over the other (Fetters et al., 2013). This would not fit well with the pragmatic philosophical approach of this study, whereby quantitative and qualitative data are valued equally. Integrating the findings in this study was justified on the basis of complementarity (each method addressed different aspects of the same question) and expansion (as both methods provide different information related to the question) (O'Cathain et al., 2007a).

Alternatively, merging by data transformation involves a process of quantifying narrative frequencies and / or qualitising numeric data (Teddlie and Tashakkori, 2009; Sandelowski, 2000a). Data transformation was considered for this thesis and it was possible to count narrative statements from the 20 interviews. This would allow the data to become more readily comparable, however there is little available guidance for this method (Plano-Clark et al., 2010). The value of data conversion in terms of advancing inquiry also has its critics (Sandelowski, 2010). Sandelowski (2010) described the unidirectional process of reducing qualitative data to dichotomous variables as problematic. Furthermore, exploratory, predictive or confirmatory statistical analysis of qualitative data sources is reliant upon an adequate sample size (Bazeley, 2012). The small available sample size for this study limited the prospect of any meaningful statistical analysis of narrative data and was therefore abandoned as unproductive. Similarly, harvesting meaningful narrative detail from numerical responses would be heavily reliant upon assumption and judgement leading to questionable credibility. Therefore, qualitising the quantitative data was also considered to be a superfluous exercise. Furthermore, there is a tendency for quantification to favour quantitative methodology and vice versa leading to a potential unwanted imbalance in methodological priorities.

Data integration of the quantitative and qualitative results can occur through the use of data displays (Guetterman et al., 2015; Creswell, 2011). The use of a visual joint display to provide a structured and coherent means of combining data together, in a visible way to enable new insights to emerge, was the preferred and most appropriate option for this study. A joint display provides a method to;

> *'integrate the data by bringing the data together through a visual means to draw out new insights beyond the information gained from separate quantitative and qualitative results'* p2143 (Fetters et al., 2013)

This avoids the vagaries of data conversion and allows the worthiness of each data set to be recognised independently. The fit of integration illustrates the degree of coherence between the quantitative and qualitative findings. Confirmation from each data set by the other enhances the credibility of the results. Whereas, 'discordance' describes contradiction between the data findings. 'Expansion' may occur when findings from the data sets diverge and so enhance insight of the phenomenon (Creswell and Plano-Clark, 2007). However, analysis and integration of different datasets can be challenging, and discrepancies in data comparison difficult to resolve. Strategies such as conducting further data collection, revisiting the original database, reference to the literature and theory for explanations, and/or challenging the validity of the constructs involved may be necessary (Creswell and Plano-Clark, 2007; Pluye et al., 2005). Discrepancies emerging from the data sets in this study, that could not be resolved by thematic expansion, are presented below and discussed in light of the current literature in Chapter 7.

Guetterman et al. (2015) categorised several exemplar joint displays. Convergent MMR designs favour 'statistics by themes' and/or 'side by side' and/or 'cross case' comparison joint displays. This study employed statistics by themes within a modified cross case comparison joint display. Cross case joint displays such as that used previously by Dickson et al. (2011), merge the quantitative and qualitative data according to individual participants. As the purpose of data merging for this study was to confirm or refute the emerging typologies and theoretical approach, the joint displays were based upon the four types of decision-making, rather than individual participants.

6.2.1 Developing The Joint Display

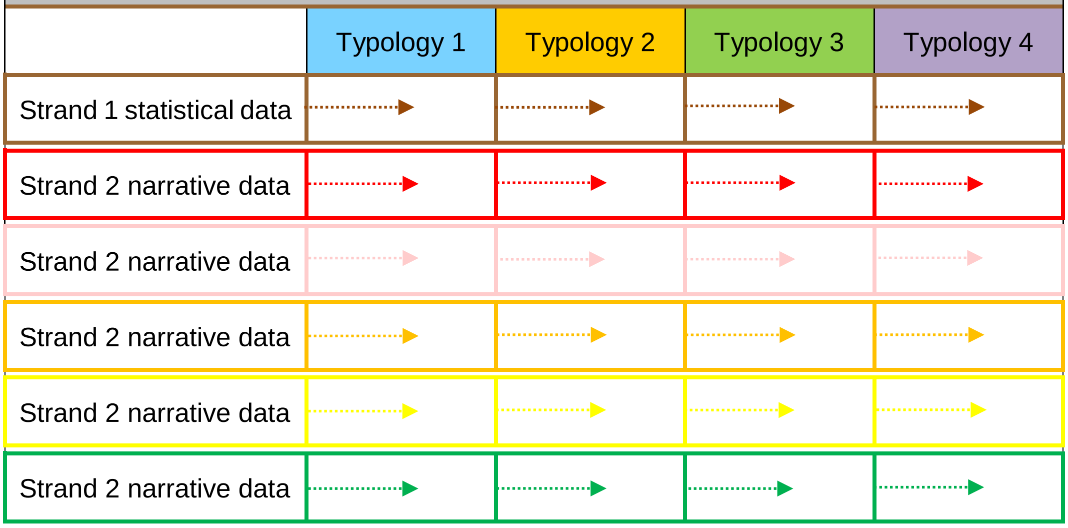
Following independent quantitative and qualitative analysis, the Strand 1 and 2 data sets were mixed by combining them in to a single Strand 3 data set. Merging the data in to joint displays was not without its challenges. Firstly, the design and organisation of the matrix required some careful planning to ensure that the display was concise and comprehensible. The data was vast and required careful selection of pertinent issues directly related to the research questions without losing sight of the valuable patient experience. Secondly, grouping variables from one data set with another so that meaningful comparisons could be made was complicated. Reference to the underpinning conceptual map (Figure 6.2), and a firm focus upon achieving the research aims were instrumental in constructing the display.

The Strand 3 data set was confined to the sample (n=20) who had completed both strand 1 and 2 elements. This was to avoid confounding analysis by introducing personal characteristics from Strand 1 that may not have been evident in Strand 2. This also meant that in order to reflect only the participants included in Strand 3, the Strand 1 numerical data was subject to further statistical analysis. Comparison of continuous variables such as mean age and monitoring scores, and dichotomous categorical variables such as high and low age categories, monitoring scores and aptitude for HL across the typologies was undertaken. Pearson's Chi square was applied to determine whether there was any significant variance in characteristics, such as gender, age category, NYHA, high / low monitoring, heuristic and systematic information processing, level and match of desired and actual participation, across the typologies. ANOVA was used to determine whether a significant difference in mean age and mean monitoring scores existed between the types of decision-making. As previously alluded to, the restricted sample size increases the possibility of type I errors, therefore findings were viewed with some caution.

Three joint displays were developed to represent the main findings emerging from Strand 1 and 2. The emergent typologies of decision-making, from Strand 2 became the focus of integration. It was hoped that integration of the quantitative and qualitative data analysis might further illuminate the key reasons why participants appeared to polarise towards one decision path or the other. Kluge (2000) advocates the development of a multidimensional table to represent the elements of each typology, and so illustrate the potential combinations and irregularities, and allow further analysis of the groups to ensure internal homogeneity and allow reduction or elaboration. The joint displays fulfilled this purpose.

Colour coding was applied to enhance visual clarity. The four typologies of decision-making highlighted in different colours (blue, orange, green and purple), are presented in the first row across columns 2 to 5. The first column signposts the strand 1 and 2 findings (Table 6.1).

Table 6-1 Colour Coding Key Used For Joint Displays



	Typology 1	Typology 2	Typology 3	Typology 4
Strand 1 statistical data	→	→	→	→
Strand 2 narrative data	→	→	→	→
Strand 2 narrative data	→	→	→	→
Strand 2 narrative data	→	→	→	→
Strand 2 narrative data	→	→	→	→
Strand 2 narrative data	→	→	→	→

Joint display 1 portrays the socio-demographic characteristics of the four emerging types of decision-making (Table 6.2). Joint display 2 illustrates the integration of findings related to ‘the process of decision making’ (Table 6.3). Joint display 3 displays integration of findings related to information exchange and recall (Table 6.4).

For joint display 2, the Strand 1 findings derived from the conceptual map, such as symptom severity and monitoring scores are colour coded with a brown border. Quantitative numerical data is organised by typology in the adjacent cells. The main themes emerging from Strand 2 are differentiated by the various colours used in Chapter 5. For example, ‘the recommendation’ is red and ‘mapping the landscape’ is pink. The sub-themes featured across the adjacent row are colour coded according to the main theme. Qualitative summaries and quotes from group participants feature within adjacent cells according to the type of decision-making. Some sub-themes do not have corresponding quantitative data but were included to provide narrative depth for the theme. This facilitated a clear and detailed understanding of each stage of the decision process. The third joint display was constructed in the same way as joint display 2 and illustrates the integration of findings related to ‘information exchange and recall’. Column 1 signposts the strand 1 and 2 findings. The four typologies of decision making (blue, orange, green, purple), are presented in the first row across columns 2 to 5. The Strand 1 quantitative findings, including aptitude for health literacy, the source of information, the cardiac condition, device type and recall of topics discussed are colour coded brown. Quantitative numerical data is organised by typology in the adjacent cells. The Strand 2 themes, ‘gathering intelligence’ and ‘the devils in the detail’ were colour coded in shades of blue. Influential factors were woven into the joint displays to provide greater insight and understanding of the participants experience.

Table 6-2 Joint Display 1 Socio-Demographic Characteristics

Joint Display 1	**Socio-demographic Characteristics**			
Conceptual Framework ↓	**Typologies**			
	'Leap Of Faith' n=8	**Reinforced Acceptance n=7**	**Reconsideration n=2**	**Reinforced Refusal n=3**
	L2 Male 56yrs IHD ICD L3 Female 74 yrs IHD CRT-D S8 Female 80yrs HF CRT-P W15 Male 62yrs IHD ICD W18 Male 61yrs NIDCM CRT-D W20 Male 73yrs IHD CRT-D L27 Male 64yrs IHD ICD L28 Male 56yrs IHD ICD	L4 Female 60yrs HCM ICD S6 Male 50yrs HCM S-ICD W12 Male 58yrs IHD ICD C17 Male 56yrs IHD CRT-D C21 Male 71yrs NIDCM CRT-D S35 Female 45yrs HCM CRT-D S44 Female 61yrs HCM ICD	L11 Male 49yrs HCM S-ICD L34 Male 68yrs IHD ICD	L9 Female 67yrs IHD CRT-D L22 Female 34yrs ARVC ICD L26 Male 55yrs HCM ICD
Gender	Male = 6 Female = 2	Male = 4 Female = 3	Male = 2	Male = 1 Female = 2
	χ2=2.94; df=3; *p* =0.56			
Age	M=65.75; SD 8.89	M=57.29; SD 8.32	M=58.50; SD 13.44	M=52.00; SD 16.70
	f =1.60; df=3; *p* =0.23			
Age Category	≤65 = 5 (62.5%) ≥66 = 3 (37.5%)	≤65 = 6 (85.7%) ≥66 = 1 (14.3%)	≤65 = 1 (50.0%) ≥66 = 1 (50.0%)	≤65 = 2 (66.6%) ≥66 = 1 (33.3%)
	χ2=1.43; df=3; *p* =0.74			
Cardiac Condition	Known IHD = 6 NIDCM = 1 HF Only = 1	Known IHD = 2 NIDCM = 1 HCM/ARVC = 4	Known IHD = 1 HCM/ARVC = 1	Known IHD = 1 HCM/ARVC = 2
Device Type	ICD = 4 CRT-D = 3 CRT-P = 1	ICD = 4 CRT-D = 3	ICD = 2	ICD = 2 CRT-D = 1

Table 6-3 Joint Display 2 The Process Of Decision-making

Joint Display 2	**The Process Of Decsion-making**			
Conceptual Framework And Themes ↓	**Typologies**			
	'Leap Of Faith' n=8	**Reinforced Acceptance n=7**	**Reconsideration n=2**	**Reinforced Refusal n=3**
NYHA Assessment Of Severity Of Symptoms	Minimal Symptoms = 0 Moderate Symptoms = 2 (25%) Marked Symptoms = 6 (75%)	Minimal Symptoms = 2 (28.6%) Moderate Symptoms = 0 Marked Symptoms = 5 (71.4%)	Minimal Symptoms = 0 Moderate Symptoms = 0 Marked Symptoms = 2 (100%)	Minimal Symptoms = 1 (33.3%) Moderate Symptoms = 2 (66.7%) Marked Symptoms = 0
	χ2=10.69; df=6; *p* =0.05**			
The Recommendation	→ **Severity Of Symptoms** All but two described experiencing significant symptoms			
Severity Of Symptoms	'They were really severe as in you were (demonstrates by gasping) aghh aghh aghh like for 5 hours' L2	'I couldn't breathe I felt like I was drowning' S44	'I really felt shocking and really was struggling just to get through day to day' L34	'It's like having your chest filled with concrete because you breathe in but there's nowhere for it to go and so you have this panic and at that point you then start to cough and then this liquid is coming up and you are coughing' L26
The Recommendation	→ **The Shock Of It**			
Shock, Fear, Surprise And/Or Matter Of Fact, Relief	Shock ± fear = 4 (50%) Matter of fact = 3 (37.5%) Relief = 1 (12.5%) 'This sudden death thing it shocked me at first' L28	Shock ± fear = 5 (72%) Matter of fact = 2 (28%) Shock tempered with relief = 2 'Scared, I didn't know what to think really but I were scared' S6 'Just a bit of a shock that you know' W12	Matter of fact = 2 (100%) 'Feels like abstract information processing and then you have the realisation that it actually applies to you' L11	Shock + fear = 3 (100%) 'I think I was just scared' L9
Worry	'I don't hit the panic button easily' W15	'I went in to some sort of anxiety and I did end up back in hospital with a panic attack' S44	'There's no point getting worked up about all that kind of stuff you have to be a bit philosophical' L34	'That puts me in to a panic and then the worrying and the stress of the worrying gives me palpitation' L22

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
The Recommendation	→ **Perception Of Clinical Need**			
Participant Perception Of Clinical Need	'This was like a matter of life and death, wow, this is just a whole new ball game now yeah and that kinda stuck with me' L2 'You are at risk of sudden death you start thinking Phhh maybe it is a little bit more serious' L28	'We had a look at the algorhythm with the degree of heart failure and the left bundle branch and the degree of irregularity and ventricular pacing etc and mine was down there clearly requiring a defibrillator version' C17	'It was unequivocal and so it was clear that I had some arrhythmia and in fact actually I had a specific episode' L11	'Are we sort of bringing out sort of the big guns to fight something that might not need that' L26
The Recommendation	→ **Strength Of Recommendation**			
Perceived Strength Of Recommendation	'I wasn't pushed, I was you know, advised (emphasised) if you like in a very pleasant way' W15	Listening to what they had said about the cardiac arrest bit and the risks there I think I would have gone at the very least for a defib you know' S35	'I was sort of borderline ish, it may not be the end of the world if I didn't have one fitted' L34	'There's no new evidence to me as to why I should have one put in' ... 'It's only factoring in at the moment because it's so, to me weak' L22
The Recommendation	→ **Immediate Decision**			
Immediate decision	'So I thought well yeah, I'll go with it' L27	'Once it had been mentioned I wanted to go ahead with it' L4 'I told them straight away that I wanted it done' S6	'So yeah I was sort of more or less open to positive suggestion' L34	'And so of course I said no I'm not agreeing' L22 'Is L26 going for this he would have probably said no it doesn't sound like he is' L26

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Mean Monitoring Score	M=28.75 (SD=8.62)	M=43.86 (SD=7.56)	M=44.50 (SD=10.61)	M=50.67 (SD=3.79)
	f=7.84; df=3; *p* =0.002**			
Low / High Monitoring	Low = 7 (87.5%) High = 1 (12.5%)	Low = 0 High = 7 (100%)	Low = 0 High = 2 (100%)	Low = 0 High = 3 (100%)
	χ2=16.15; df=3; *p* =<0.001**			
Heuristic ± Systematic Information Gathering	Heuristic = 7 (87.5%) Systematic = 1 (12.5%)	Heuristic = 1 (14.3%) Systematic = 6 (85.7%)	Heuristic = 1 (50.0%) Systematic = 1 (50.0%)	Heuristic = 1 (33.3%) Systematic = 2 (66.7%)
	χ2=8.41; df=3; *p* =0.02**			
Mapping The Landscape	➡	**Thinking Fast**		
Expert Opinion	'I rely on the expert advice of people and that makes me feel comfortable, it makes me feel calm and well the rest is easy passed that point' W15	'I'll obviously take clinical guidance, you're bound to aren't you .. Because you hope that the expert does have some credibility in their recommendations don't you?' C17	'Your still in a more informed position than I am what would you do? And he gave me his' L11	'To me it was my cardiologist saying I think you need one which kind of freaked me out because obviously you know I take their opinion very seriously because they are the experts' L22
Availability Heuristic Thinking	'When I first mentioned it, this old guy Fred he said Oh yeah look there's mine there look touch it and you think oh right. He was saying best thing I ever had done, I mean that sort of thing as well I mean it's endorsing my decision to have this thing done' L28	'He'd been led to believe, not by nurses but by other people that had pacemakers and jungle telegraph that he'd be superman' C21	'You talk to people with these inherited conditions, you've got two choices, you can either learn to live with it or you can not ignore it but sort of park it out of the way' L11	'He was a strong man well I thought if he wishes he'd never had the defibrillator put in well then it must be. Me your not the type of person that would manage with it' L9
Mapping The Landscape	➡	**Thinking Slow**		
Systematic Information Processing	'No and I don't google. A little bit of information is a dangerous thing I think. I'd better just rely on the experts' L3 'I didn't do any research at all, no just my gut feelings and discussions with my wife' L27	'Going on internet, Googling and everything as soon as she mentioned' S6 'All the queries that I had they answered straight away or I found out myself and as I say there's plenty of publications and that' W12	'I really went straight on to the British Heart Foundation and things yeah and you know and chatting with one or two people' L34	'I did look in there (*CMA*) as I'd looked up that condition already as well but I really went in and looked up sites that came up when you put in the device' L26

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Planning The Journey	→ **Fear Of Death And Prolonging Life**		**Tipping The Balance**	**Prioritising Quality Over Quantity Of Life**
Prioritising Quantity And Quality Of Life	This group prioritised living longer and preventing an early death over all else. 'At least if you've got your defibrillator and you do go in to cardiac arrest at least it'll keep you alive' W18	The desire to live longer and prevent an early death was important to this group but not without consideration of the potential harms and risks of CRMD. 'If I can't go running round then well that's fair enough but at least I'll be seeing tomorrow morning' W12	Quantity and quality of life was in the balance. ICD therapy was 'parked at a distance' L11 and 'I'd pretty much made up my mind that I wasn't going to get it fitted because of that, it just wasn't a tolerable thing for me' L34. Until the increased risk of SCD became more evident tipping the balance in favour of device therapy. 'Until that point I was someone who had this notional risk, then once you are scheduled to have an ICD it's that sudden cardiac death bit which is the focus and not the symptoms' L11. 'The clinching thing was nurse said look if you had one of these ventricular arrhythmia or whatever nurse said it will almost certainly kill you' L34	Conversely, the impact of potential undesirable consequences associated with device therapy upon quality of life took precedence for this group. 'If I'm gonna die I'm gonna die I don't want foreign bodies in me, inside me' L9
Planning The Journey	→ **Balance Of Benefit And Harm**			
Considering The Potential Benefits & Risks Of Device Therapy	'There didn't seem to be any cons to having it done. I don't know whether there are any because nobody mentioned that there could be problems' L3	'I think the risk of not having it done far outweighed any risk of you know the surgery or what have you' W12	I said to my wife I'm not going to have it fitted you know, if I have a heart attack I have a heart attack but frankly I can't cope with the consequences of all that you know' L34	'How I'm viewing an ICD is that yeah the longer you have it the more risk of complications therefore you don't want to have it until you really need it' L22 'The potential complexities and risks associated with it don't seem to be warranted given how my heart appears to be performing now' L26

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Social Issues	Driving = 5 Sport = 2	Driving = 6 Sport = 3	Driving = 2 Sport = 2	Driving = 2 Sport = 1
Driving Issues	'Sad, yes it blooming well did because I've got a classic car in my garage and I'm very upset. Yeah, now I'm very upset' W15 'I think it was probably the 4 weeks not driving' L27	'One thing that is still at the back of my mind is driving, it does concern me a little bit' L4 'Stupidly the one thing that I got upset about was the driving' S35	'Then you get to the bit on driving and oh my goodness. It said if the device was ever triggered even for just a pacemaking function then you can't drive for another 6 months, now I really shuddered out of horror because it's a complete life changer for me that'... 'It just wasn't a tolerable thing for me' L34	'I've got a lot of commitments and I have been told that I couldn't drive again' L9
Device Size Concerns	'I didn't realise it was that size I thought, it's about as big as a pocket watch' L27	''The only down side is that it's bigger isn't it and ICD Nurse said because I'm relatively small it's noticeable' C17	'There was quite a big tipping point between the subcutaneous option and the transvenous option' ..'It's probably a bit larger because it's about the size of an Iphone and so a bit larger than the transvenous' L11	'The S-ICD is bigger than the normal ICD but it's already 20% smaller' L22
Shock Therapy	'I've got a defibrillator which jumps in when my heart beat gets a bit erratic, now if that jumps in would I feel it? because I've never felt it, a little punch?' L3	'That's not a problem to me I don't want it to go off, I don't even especially think about it going off actually' C17	'It is a factor that I've thought about instead of having a nice quiet death probably whatever happens now I'm going to have a death which is repeated belts in the chest' L11	'I knew that when they give you a shock, they give you a shock as your whole body goes rigid and I thought, no if that was to happen to me outside I'd be mortified' L9

	'Leap Of Faith' n=8	**Reinforced Acceptance n=7**	**Reconsideration n=2**	**Reinforced Refusal n=3**
Desired Participation	Active = 6 (75%) Passive = 1 (12.5%) Collaborative = 1 (12.5%)	Active = 5 (71.4%) Passive = 1 (14.3%) Collaborative = 1 (14.3%)	Active = 2 (100%) Passive = 0 Collaborative = 0	Active = 2 (66.7%) Passive = 1 (33.3%) Collaborative = 0
	χ2=1.89; df=6; *p* =1.00			
Actual Participation	Active = 7 (87.5%) Passive = 1 (12.5%) Collaborative = 0	Active = 7 (100%) Passive = 0 Collaborative = 0	Active = 2 (100%) Passive = 0 Collaborative = 0	Active = 3 (100%) Passive = 0 Collaborative = 0
	χ2=1.58; df=3; *p* =1.00			
Match Between Desired & Actual Participation	Match = 7 (87.5%) No Match = 1 (12.5%)	Match = 5 (71.4%) No Match = 2 (28.6%)	Match = 2 (100%)	Match = 2 (66.7%) No Match = 1 (33.3%)
	χ2=1.44; df=3; *p* =0.76			
Marital Status	Married = 5 Single = 1 Divorced = 1 Widowed = 1	Married = 6 Divorced = 1	Married = 2	Married = 2 Single = 1
	The surveys found that generally women did not refer specifically to their partner for information or advice, whereas men did revealing a significant gender difference (χ2 =4.91; df=1; p=0.04**)			

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Travel Agency	**Passive Or Active Decision-making**			
Family Influence	Four men referred to wife's opinion The married women did not rely on husbands opinion Family did influence the other three	3 men referred to wife's opinion, 1 did not comment. Two married women did not rely upon husbands opinion Family influenced the other female	1 man referred to wife's opinion, the other did not	1 man referred to wife's opinion Family influenced one female
Travel Agency	**Collaborative Participation**			
Collective Participation	'Well he he decided to put me name down' 'I couldn't go against, the way I think about it is if you are talking to a doctor and a doctor explains some'at to you and it sounds good why would you think of, why would you even think of saying no' L2	'ICD Nurse didn't make the decision for me but he gave me the facts and discussed in depth and I was even more sure that I wanted to go ahead with ICD' L4	'So yeah the two long conversations with nurse really were the key factors in completely turning me 180 degrees about and bringing me on board with obviously what the consultant thought was right' L34	'It's very much down to like here's the information and I'm going to present it in a way that I hope you will take seriously or whatever but it's kind of up to you' L22
Perceived Level Of Control Over Ultimate Decision	'No, no er ICD Nurse, no no ICD Nurse, yes me and my wife spoke about it and it was just a no brainer not to have it done' L2	'I had kind of made my decision before I met ICD Nurse' L4	'I absolutely feel that I was allowed to make the decision, I was given all the support that I needed to help me make the decision' L11	Where I quizzed him was on this VT stuff because critical to my decision was me trying to make my mind up about actually what had happened and how serious potentially that was' L26

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Endorsing The Decision	→ **Security Or Stressor**			
The Meaning Of Technology - Security Or Stressor	'It was just a no brainer not to have it done' ... 'It’s like being in the AA your car might never break down but at least you’ve got cover in the AA, It shows you that bit more peace of mind' L2 'It’s there if, like a safety net' W18 ‘I’m always forever the optimist, my glass is always half full sort of thing you know so I have a bit of a heart problem but as long as I take it easy and steady I should be alright you know and not over do it' L28	'I felt it was like a security blanket' L4 'It’s like walking with a paramedic inside you all the time waiting for something to happen' S6 'Having an additional protection, why are you going to have a problem with that' ...' It was straight forward, no brainer, literally' C17	'In terms of accepting, going for the defib it was removing the cloud, the risk' ...' 'It was in the balance. Yeah I think in retrospect now looking back I’m very happy to have the reassurance' L11 ''Nurse said to be brutally honest it’s a Hobson’s choice, you know nurse said you are damned if you do or damned if you don’t' L34	'I churned it over and I churned it over and, if you want to sit there and be a veg fair enough you can do it that way but I don’t want to be frightened of doing anything' L9 'What you re dealing with is a device that makes its own judgment about when it needs to do things and that inevitably must mean that occasionally that may misinterpret what is happening and act in a way that doesn’t help you' L26
Endorsing The Decision	→ **Optimism Bias And Taking Control**			
Belief In Low Risk And Maximising Self Control	'You may not even notice that its gone off, that’s it’s done it W15 'I don’t need it, if I’d have needed it then fine there’s no two words about it you get it done' W18	'I did think is it (ICD) a bit of an over reaction, because you know I thought it only is a low risk' L4 'So now it’s a matter of just trying to get a bit healthier' S35	'It’s a load of fuss over this notional thing which may or may not happen' ....'I’ve always kept myself fit, tried to minimise my controllable part of the risks, I haven’t let it control me' ...'now that I’ve got the security blanket what I can do to actually recondition myself hopefully to minimise symptoms' L11	'I’m keeping fit but also having modified my lifestyle in terms of I don’t do strenuous exercise, luckily I’ve never done any illicit drugs and I think the third one he said was to avoid high levels of emotional stress. I have made modifications in terms of the work that I do and what I try and fit in to a day' L22 'I am on a whole lot of medications which I think further provide me a buffer of protection' L26

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Decisional Outcome	→ Accepted M= 8.23 (SD=11.87)		Declined M=10.0 (SD=8.16)	Mann Whitney *U* *p*=0.62
	Regret M=9.37 (SD=11.30)	Regret M=6.42 (SD=13.81)	Regret M=10.0 (SD=8.16)	Regret M=10.0 (SD=0)
Doubt Or Regret	'I don't regret having it done now' S8 'On the day when I was having it done she was saying have you any regrets I says no I don't think so' W18 'I thought well if I don't have it and something happens I'm going to regret that decision' L27	'I've no regrets, no no regrets at all thankfully' L4 'Other than feeling a little disappointed that I don't feel much better than I do, that's the only regret I have' C21	'No doubt about anything, I'm nearly 50 and I've had a brilliant life so far and I'm probably going to live for another 20 something years I hope, touch wood' L11 'If I had decided at the time a few months ago not to go through with it I would probably be regretting it by now' L11	'I' don't regret it, no' L9

Table 6-4 Joint Display 3 Information Exchange And Recall

Joint Display 3	**Information Exchange And Recall**			
Conceptual Framework And Themes	**Typologies**			
	'Leap Of Faith' n=8	**Reinforced Acceptance n=7**	**Reconsideration n=2**	**Reinforced Refusal n=3**
Low / High Aptitude For Health Literacy	Low = 5 (62.5%) High = 3 (37.5%)	Low = 2 (28.6%) High = 5 (71.4%)	Low = 0 High = 2 (100%)	Low = 1 (33.3%) High = 2 (66.6%)
	χ2=3.46; df=3; *p*=0.43			
Source Of Information - Survey	Consultant only = 4 Consultant & ICD / HF Nurse = 4	Consultant only = 1 Consultant & ICD / HF Nurse = 6	Consultant only = 1 Consultant & ICD / HF Nurse = 1	Consultant only = 0 Consultant & ICD / HF Nurse = 3
Gathering Intelligence	**The Consultation Process**			
Source Of Information - Int.	Consultant only = 5* Consultant & ICD / HF Nurse = $3^{\#}$	Consultant only = 0 Consultant & ICD / HF Nurse = $7^{\#}$	Consultant only = 1 Consultant & ICD / HF Nurse = 1	Consultant only = 1* Consultant & ICD / HF Nurse = 2
* Indicated ICD nurse on Q not evident at interview (n=2). $^{\#}$ Did not indicate ICD nurse on Q but was evident at interview (n=1)				
Conultant Only - 2 of 6 well informed. Consultant + Nurse - 11 of 14 well informed. Proportionality Z test score = 1.96 equal to pre-set Z score of 1.96 @ *p* 0.05. Marginal signifcant difference noted.				
Gathering Intelligence	**The Professional Approach**			
The Professional Approach	She said it in laymen's terms you know what I mean she didn't go around corners she just told us it as it was you know' W18	I quite liked it because she was quite frank and open and no wishy washy, this is what it is, you need to know these facts because you need to make a decision , for me that is perfect, I don't want it glossed over' S35	'I had a fairly frank conversation with Consultant' L11 'Yeah very blunt but you know nurse was' L34	'I spoke to ICD Nurse and he was excellent, he took me all the way through it and explained everything, that was absolutely brilliant' L9

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Gathering Intelligence	**A Positive Spin**			
A Positive Spin	'We talked about the pros I've got to say more than the cons' L3 'It never made me once think maybe not, everything was positively channelled in to what I was going to have done' L28	'It was mainly the heart failure nurse that explained that my heart wasn't synchronised and it couldn't pump as well and if it was synchronised I'd probably feel better' C21	'So nurse said to be brutally honest it's a hobson's choice, you know nurse said you are damned if you do or damned if you don't so quite frankly you might as well accept the living option and accept the 6 months if it goes off as accept the death option' L34	It does speak for the power that they have got because if they, they can influence massively someone's decision with the language they use, the seriousness with which they approach it' L26
Cardiac Condition	All indicated the correct cardiac condition			
The Devil's In the Detail	**Cardiac Condition**			
Knowledge Of Cardiac Condition	**Full Aware = 2 Partial = 4** **Misunderstanding = 2** 'That caused my heart to enlarge so it caused cardiomyopathy, OK. The Dr actually at the time just said to me, he says it's because your hearts been over working, it's your heart muscles have stretched so in other words instead of like a balloon, you blow a balloon up, let it down, blow it up, let it down and eventually it goes baggy and loses it's tautness. Well that's what my muscle had done' W18 'I don't know whether it was a small heart attack or heart failure, I don't know what it was' L3	**Fully Aware = 6** **Partially Aware = 1** **Misunderstanding = 0** 'That was probably the first time I had properly understood the left bundle branch block bit because that's obviously contributory to the decision about the defibrillator' C17	**Fully Aware = 2** **Partially Aware = 0** **Misunderstanding = 0** 'The group of people that I am in having had two heart attacks is a significant risk of a third' L34	**Fully Aware = 2** **Partial Aware = 1** **Misunderstanding = 0** 'The left and right, the left ventricle of my heart wasn't functioning as it should be and it was sort of like fighting against each other and of course with it not working in sync with the other side of my heart, was making one side of my heart really weak and tired' L9

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Device Indication	Correct = 3 Incorrect = 5	Correct = 3 Incorrect = 4	Correct = 2 Incorrect = 0	Correct = 2 Incorrect = 1
The Devil's In the Detail	**Device Indication, Type, Role And Function**			
Knowledge Of Device Indication & Type	**Correct = 0 Partially Correct = 5** **Incorrect = 3** 'Well I just thought that it was like an improved version of the pacemaker' .. 'There's all four leads I think, five yeah, I don't know is it four or five' W20	**Correct = 7 Partially Correct = 0** **Incorrect = 0** 'I've got the pacemaker and defib device for two reasons. One to try and alleviate the symptoms that I was feeling, so the function of the heart, and then the defib was because the function of the heart was so bad that I was at high risk of cardiac arrest' S35	**Correct = 2 Partially Correct = 0** **Incorrect = 0** 'When it was almost like the fall back position of the S-ICD rather than the TV that was for me that was kind of let's get it over with' L11	**Correct = 2 Partially Correct = 1** **Incorrect = 0** 'If you're at risk of cardiac arrest this is when we would implant an ICD but of course the issue is when and ARVC is a funny one in terms of there is always a small risk of cardiac arrest, but at what point do you put it in is a grey area' L22
Knowledge Of Device Role & Function	**Correct = 1 Partially Correct = 5** **Incorrect = 2** 'It's got 2 wires it can differentiate between being out of breath walking up a hill or strenuous exercise as to a life threatening heart rhythm' L28	**Correct = 7 Partially Correct = 0** **Incorrect = 0** 'They never said that this would cure the AF it was just a resynchronisation' C21	**Correct = 2 Partially Correct = 0** **Incorrect = 0** 'There were two reasons both protective, there was sort of a 10% per annum likelihood of having a further heart attack and this thing might save my life' L34	**Correct = 3 Partially Correct = 0** **Incorrect = 0'** 'The defibrillator just acts like it normally does, like you would see on TV that it shocks you whenever your heart needed to be shocked' L9
Benefit & Risk Of Accepting Device	All indicated on questionairre that discussion had taken place			
Benefit & Risk Of Refusing Device	5 indicated on questionairre that discussion had taken place	5 indicated on questionairre that discussion had taken place	All indicated on questionairre that discussion had taken place	All indicated on questionairre that discussion had taken place
Recall Of Discussion Regarding Benefits And Risks Of Device Acceptance & Refusal	'He talked about pacemaker which you know might help your quality of life but he didn't talk about anything else really' L3	'*Did she talk about the risks to you of having the defibrillator?* Yes she went through everything' C17	'He went through all of the issues that could arise from the actual medical procedure for the actual fitting, things that could go wrong but said you know they fit dozens of these things all the time and you know they are really very rare and that I shouldn't worry from that point of view, then gave me a booklet and packed me off home'L34	'It just told me really and truthfully exactly what the hospital had told me that it would make my life better if I would try it' L9

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Physical Issues	Recalled = 6 Not recalled = 2	Recalled = 5 Not recalled = 2	Recalled = 2 Not recalled = 0	Recalled = 2 Not recalled = 1
The Devil's In the Detail	**Awareness Of Physical, Emotional And Social Impact**			
Aware Of Potential Procedural & Post Implant Physical Complications i.e. Infection	**Recalled = 1** **No or inaccurate recall = 7** 'He mentioned that there's always the potential with anything manmade giving a problem however they're so slight or like 1 in so many thousands times it could happen' L2	**Recalled = 5** **No or inaccurate recall = 2** 'It's surgery at the end of the day and such as that and there's always a risk yeah they covered all that' W12	**Recalled = 2** **No or inaccurate recall = 0** '*Were you are aware of the possible complications that there are with them?* Yes I like to think so anyway but I don't want a list' L11	**Recalled = 2** **No or inaccurate recall = 1** 'Talking to ICD Nurse was that obviously he sees them when they go wrong and that's basically a lot of what he sees so it was really interesting to get his view point on all the complications' L22
Emotional Impact	Recalled = 5 Not recalled = 3	Recalled = 4 Not recalled = 3	Recalled = 1 Not recalled = 1	Recalled = 2 Not recalled = 1
Discussed Potential Emotional Impact	**Recalled = 2** **No or inaccurate recall = 6** 'I struggled with that for a little while, more psychological than anything else. *Did anyone talk to you about possible psychological feelings?* Yes, err I can't remember his name now' L27	**Recalled = 2** **No or inaccurate recall = 5** 'My wife had listened to a radio programme that was talking about people being depressed and anxious because they've got this thing that can go off' C17	**Recalled = 2** **No or inaccurate recall = 0** 'Nurse said it probably isn't going to affect your day to day life or make you feel any better other than psychologically perhaps nurse said because you've got some reassurance' L34	**Recalled = 2** **No or inaccurate recall = 1** 'He pointed out that some people who have them implanted have the opposite psychological impact, that they are worrying that they are going to go off' L22
Social Issues	Recalled = 6 Not recalled = 2	Recalled = 6 Not recalled = 1	Recalled = 2 Not recalled = 0	Recalled = 3 Not recalled = 0
Discussed Social Issues i.e. flying, sexual activity, sport	**Recalled = 3** **No or inaccurate recall = 5** 'I forgot to ask him, you'll know you might be able to help. How long is it before you can fly, go on an aeroplane?' S8	**Recalled = 6** **Not recalled = 1** 'Exercise there's a bit of a bleary thing that I keep asking about exercise and I know Dr X did tell me to go ahead and exercise because your hearts muscle and it needs exercise but only moderate exercise don't go mad' S44	**Recalled = 2** **Not recalled = 0** 'Now that I've got the security blanket what I can do to actually recondition myself hopefully to minimise symptoms' L11	**Recalled = 3** **Not recalled = 0** 'I like swimming, quite a lot things I do on my own and if I had a cardiac arrest and the device shocked me if I'm still in water it's still an issue, I've still got the issue of drowning' L22

	'Leap Of Faith' n=8	Reinforced Acceptance n=7	Reconsideration n=2	Reinforced Refusal n=3
Home Or Work	Recalled = 3 Not recalled = 5	Recalled = 4 Not recalled = 3	Recalled = 1 Not recalled = 1	Recalled = 3 Not recalled = 0
Discussed Potential Impact Upon Daily Home Or Work Related Activities	**Recalled = 3** **No or inaccurate recall = 5** 'He said well really you should be avoiding the welding, so I've had to change that, I don't go in there very often now' L27	**Recalled = 6** **No or inaccurate recall = 1** 'I knew with regards the information that they give you with regards to work that it would seriously affect the job that I did work wise' W12	**Recalled = 2** **No or inaccurate recall = 0** 'We talked about all sorts of ramifications now in terms of would we be able to move again or even where you can live, where you can work, there would be implications in terms of occupational health' L11	**Recalled = 3** **No or inaccurate recall = 0** 'I'd be sat at home all the time and that is not me, I wouldn't have any life at all' .. 'I mean I'm always fiddling, crocheting, knitting, walking dogs, cleaning so you know it's part of my life, I couldn't be one that just comes home, sits down, has my tea, watches the television 24/7 cos it just doesn't do me any good' L9
The Devil's In the Detail →	**Awareness Of Shock Therapy**			
Discussed Shock Therapy	**Recalled = 2 Not applicable = 1** **No or inaccurate recall = 5** 'I've got a defibrillator which jumps in when my heart beat gets a bit erratic, now if that jumps in would I feel it? because I've never felt it, a little punch?' L3 'From what would be a noticeable shock if it's a biggey, that that machine has decided it's going to be a biggey, they said you may not even notice that its gone off, that's it's done it' W15	**Recalled = 7** **No or inaccurate recall = 0** 'There is a couple of things where it tries to regulate it and then if that doesn't work it does another step doesn't it, it does another thing and then obviously it knocks you back' S44	**Recalled = 2** **No or inaccurate recall = 0** 'It can be anything up to a kick in the chest, I imagine it's going to be fairly violent' L34	**Recalled = 3** **No or inaccurate recall = 0** 'He said there's no easy way about the defibrillator, I'm just going to have to tell you what it is and he says, It kicks like a mule' L9

	'Leap Of Faith' n=8	**Reinforced Acceptance n=7**	**Reconsideration n=2**	**Reinforced Refusal n=3**
Well Informed - Low / High Level Of Recall	Low = 3 (37.5%) High = 5 (62.5%)	Low = 2 (28.6%) High = 5 (71.4%)	Low = 0 High = 2 (100%)	Low = 0 High = 3 (100%)
	χ2=2.38; df=3; *p* =0.89			
The Devil's In the Detail	→ **Feeling And Being Well Informed**			
Actual Level Of Recall	**Well informed = 0** **Partial recall = 3** **Limited recall = 5** 'I mean it's all in here and out of there but they know what they are on about' W18	**Well informed = 7** **Partial recall = 0** **Limited recall = 0** 'Dr X took a long time prior to the consent. He was very thorough and explained and went over and over what ICD Nurse had explained so you know the message was repeated in terms of the risks and the potential for it now to work' C17	**Well informed = 2** **Partial recall = 0** **Limited recall = 0** 'I phoned nurse up again about 2 weeks later because there's a whole other raft of questions then arisen you know then when you start to sway towards having it put back in again then you've got a whole load more questions that you really need to ask' L34	**Well informed at refusal = 3** **Partial recall = 0** **Limited recall = 0**
Felt Well Informed	**Felt well informed = 5** **Not evident = 3** 'I think I had all the information. As I say it's just the two things I've asked you and at the time I never thought to ask those questions' L3 'I felt very well informed, yeah that one word says it all really' W15 'I think Dr X, well she explained everything' W18	**Felt well informed = 6** **Not evident = 1** 'I think I was quite well informed making the decision' S35	**Felt well informed = 1** **Not evident = 1** 'I was probably pretty well informed just because of my nature. I approached it as I guess it was sort of like an evidence based situation' L11	**Felt well informed at refusal = 2** **Not evident = 1** 'I can't knock ICD Nurse, he took his time to tell me everything' L9 'I've never felt under informed and I've never felt umm so there's been no gap in terms of' L22

6.3 Phase 4 Meta-Inference

The final phase 4 of this mixed methods study refers to ‘meta-inference’. That is, the process of consideration and interpretation of inferences derived from all data types and the combined analyses. Meta-inference can provide confirmatory (bridging) and contradictory (bracketing) evidence, leading to new understanding of the phenomena (Klassen et al., 2012; Onwuegbuzie and Teddlie, 2003). It aspired to explain the phenomena in order to map the polarities and better understand the reasons why people fall in to different decision-making typologies (Gale et al., 2013). Thus, Strand 3 attempts to emphasise the similarities and differences that might inform decision support mechanisms for future recipients.

The joint displays facilitated the process of meta-inference in two ways. Data integration within the joint displays was used to make sense of information from both data sets. Data integration emphasised the distinct characteristic differences between the groups and so confirmed the four typologies of decision-making as;

1. *Leap Of Faith*
2. *Reinforced Acceptance*
3. *Reinforced Refusal*
4. *Reconsideration*

Concordance between the quantitative and qualitative data sets within the groups also served to validate the findings of each and further substantiate the typologies of decision-making. Secondly, data was compared between the displays to capture the overall perception and experience of the participants. This confirmed that the type of decision-making determined the level of information recall and the ability to accurately articulate their knowledge as a measure of their understanding.

This final integration and meta-inference stage also revealed discrepancies between the survey and interview responses within the group, for example symptom severity. In addition, the decision-making experience of some participants did not completely fit with the original conceptual map, for example collective participation. The concluding explanation of decision-making for primary prevention CRMD, developed through integration and inferences obtained from the qualitative and quantitative strands, are presented according to the four emerging decision-making types. Table 6.5 presents an overview of the findings.

Table 6-5 Summary Of Findings From Data Integration

Characteristics	**Leap Of Faith**	**Reinforced Acceptance**	**Reconsideration**	**Reinforced Refusal**
Age	Older adult	Mid age adult	Mid age adult	Youngest
Most Common Cardiac Condition	IHD	IHD, NIDCM or ICC	IHD, NIDCM or ICC	ICC
Self-Assessed Severity Of Symptoms	Marked	Marked	Marked	Minimal - Moderate
Perception Of Clinical Need	High	High	↓ High or Low ↓	Low
Immediate Impulsive Decision	Accept	Accept	Accept or Decline	Decline
Aptitude For HL	Lower	Higher	Higher	Higher
Monitoring Score	Low	High	High	Highest
Fast Heuristic Thinking	Positive bias	Positive and negative bias	Positive and negative bias	Negative bias
Sole Reliance Upon Consultant Information	Yes	No	No	No
Perceived Strength Of Recommendation	Strong	Strong	Unsure	Weak
Slow Systematic Information Processing	No	Yes	Yes	Yes
Prioritise Preventing SCA & Prolonging Life	Yes	Yes	Yes ↔ No	No
Prioritise Quality Of Life	No	No	No ↔ Yes	Yes
Balance Of Device Benefit & Harms	Benefits > Harms	Benefits = Harms	Benefits > Harms ↓ Harms > Benefits ↓	Harms > Benefits
Final Decision	Accept - Security	Accept - Security	Accept Decline	Decline - Stressor
Informed Decision And Consent	Not fully informed	Well informed	Well informed	Well informed

6.3.1 Confirming The Typologies Of Decision-making

During the interviews, the participants expressed feelings of shock, surprise or fear when CRMD therapy was proposed. They were faced with the sudden realisation that they had a higher than average risk of SCA. This triggered an immediate decision to accept or decline at the point of the recommendation. The recommendation and immediate decision then signified the beginning of a more considered decision-making process for some, but not all participants. Merging the Strand 1 and 2 data sets provided verification of the four emerging typologies of decision-making and the level of knowledge and recall of the participants.

6.3.1.1 The Leap Of Faith

Leap Of Faith decision-making was characterised by an immediate and resolute decision to accept CRMD implantation, based entirely upon the experts recommendation. The recommendation induced shock and fear for half of the participants in this group, and a matter of fact attitude or a feeling of relief for the others. Once they had recovered from the initial shock, the participants did not display an anxious demeanour, and described having a generally calm, 'laid back' outlook on life. They described severe symptoms, which scored as II (moderate) or III (marked) on the NYHA scale, and a perceived clinical need for CRMD to prevent an early death and prolong life was emphatic. Several factors appeared to distinguish this type of decision-making from the other three.

Participants who adopted *Leap Of Faith* decision-making were older on average (M=65.75 years) and more likely to have IHD as opposed to a non IHD diagnosis. Although the age difference was statistically significant in the Strand 1 (n=50) data, the influence of age and cardiac condition on the process of decision-making was not statistically substantiated in the Strand 3 (n=20) data analysis. This could be a consequence of the small sample tested. Nevertheless, although not statistically significant, the mean age of those who adopted *Leap Of Faith* decision-making was notably higher than the other groups. It was associated with fewer years in formal education, a lower aptitude for health literacy (HL) and lower monitoring scores. The mean monitoring scores (M=28.75) were significantly lower for this group in comparison to the other three groups (f=7.84, df=3, p=0.002). Furthermore, monitoring scores were associated with the degree to which the decision-making type engaged in systematic information processing. This group were more likely to engage in heuristic thinking only (χ^2=8.41; df=3, p=0.02) than the other types of decision-making. This was substantiated by participants in this group who described their total reliance upon the experts opinion, and for whom fast, heuristic thinking dominated an apparent uncritical acceptance of device implantation without exploring the implications further. They were persuaded by positive availability heuristic thinking. That is, referral to an instance or experience of others affecting a decision that may be positive or negative (Kahneman and Tversky, 1996). Recall of their experience or that of others was couched in positive terms by these decision-makers. What's more, they denied looking for any further sources of information to corroborate their initial decision. That is, deliberation revolved around their confidence in the experts information and advice which was sufficient reinforcement for the decision they had made. This was sanctioned only by reference to prior experience of self or others, including fictional characters such as TV.

Fifty percent of this group were seen solely by the consultant, whereas the majority of the other three groups were also seen by a specialist nurse. Data integration corroborated some similarities across the groups in terms of specific areas of knowledge. It also verified distinct differences in the overall amount and accuracy of understanding across the groups. Participants who demonstrated *Leap Of Faith* decision-making were not as fully informed as the other groups. This was supported by the participant narratives. These participants were not able to articulate details about their cardiac condition, the device indication or role and function with any clarity or accuracy. This was in stark contrast to the other groups. That said, this group verbalised their satisfaction with the sufficiency of information received and level of involvement in the decision-making process.

6.3.1.2 Reinforced Acceptance

Reinforced Acceptance decision-making was also associated with an immediate and resolute decision to accept CRMD implantation. However, this was followed by a period of slow contemplation, where participants collected additional sources of information to reinforce their decision. Shock and fear (72%) was the dominant response to the recommendation by this group of patients, though it was tempered by a feeling of relief for 2 participants. Relief was the initial reaction for the other 2 patients. However, participants, particularly the women who demonstrated *Reinforced Acceptance* decision-making described feeling anxious about the decision. They all considered their symptoms to be marked, scoring III on the NYHA scale which translated into a perceived clinical need for CRMD to prevent an early death and prolong life. This group of participants also displayed a range of distinctive characteristics.

They were younger (M=57.29 years), more likely to have a non IHD diagnosis, had >16years of formal education, a higher aptitude for HL and a higher mean monitoring score (M=43.86) than those who took the *Leap Of Faith*. Participants in this group described their desire to accept expert opinion, however this did not negate further information seeking and processing. Expert opinion was viewed in more cautious terms and reference to availability heuristics presented positive and negative biases. Nevertheless, this was considered in the context of systematic sourcing and information processing to support decision-making. Most received information from the consultant and ICD or HF specialist nurse, as well as personal sourcing of information. Reputable, professional websites such as BHF, NICE and Medtronic were referred to amidst some googling and reference to patient forum sites. Information was used to weigh up the pros and cons of device therapy.

Reinforced Acceptance decision-making was associated with prioritising staying alive and preventing SCA. However, information gathering largely appeared to reinforce the decision to accept a device, as several participants stated that their initial thoughts had never been brought in to question. There was an element of avoidance of some less pleasant information such as the actual procedure. Furthermore, although they had received written and / or verbal information related to the nature of device therapy, some did acknowledge avoidance of YouTube imagery related to shock therapy and death. Nevertheless, the participants appeared to be well informed. During the individual interviews they were able to recall and reiterate their knowledge and understanding. They provided an accurate account of their cardiac condition, indication, role and function of the device, and discussion of the device benefits and risks.

6.3.1.3 Reconsideration

In contrast, 2 participants adopted a matter of fact, open to suggestion approach to the recommendation and the initial decision made was irresolute. They also described a period of slow contemplation, where they collected additional sources of information however this served to inspire them to reconsider their initial decision. They did not consider themselves to be prone to anxiety. They considered their symptom severity to be marked (III). A low or high perception of need translated into an immediate decision to decline or accept respectively. This represented *Reconsideration* decision-making.

Reconsideration decision-making was associated with a similar age (M=58.50 years) to *Reinforced Acceptance* decision-making. One was diagnosed with IHD, and the other with non IHD. They also had >16years of formal education and a higher aptitude for HL which corresponded with their desire to gather and contemplate further information. Their high mean monitoring score (M=44.50) was similar to the group who adopted *Reinforced Acceptance* decision-making. Expert opinion was considered to be important but not absolute and referral to previous or others experience had positive and negative connotations also prompting systematic information processing. However, this group displayed more hesitance and changed their mind before eventually accepting a device. Consequently they could also describe their condition, the device and were aware of the potential benefits and risks of therapy.

6.3.1.4 Reinforced Refusal

Reinforced Refusal decision-making represents a group of participants who made an immediate and resolute decision to decline CRMD implantation. They also described a period of slow contemplation, where they collected additional sources of information to reinforce their decision in a similar way to those who used *Reinforced Acceptance* decision-making. However, there were some distinctive differences between those who accepted a device and those who declined. All three expressed feelings of shock, fear, horror and described elements of panic when the device was recommended. They appeared to be highly anxious, describing instances of anticipatory anxiety associated with device therapy. Despite the use of similar descriptors to describe severe symptoms as the other participants, they scored their symptoms as minimal (I) or moderate (II) on the NYHA scale. This translated into the perception of a low clinical need for CRMD. This group also displayed a range of distinctive characteristics.

Although a very small sample, those who declined the device were notably younger (M=52.0 years). Two were female and one male, and so they were too few to explore any potential gender influence further. Two were diagnosed with an inherited cardiac condition (ICC). They also had >16years of formal education, a higher aptitude for HL and they recorded the highest mean monitoring score (M=50.67, *f*=7.84, df=3, *p*=0.002) than those who accepted a device. Participants in this group described their desire to accept expert opinion however this did not correspond with their actions. Expert and availability heuristics presented a negative bias and induced greater curiosity. They engaged with independent, systematic information processing from professional websites which served to reinforce their decision to decline. They state that at no point had they considered changing their mind as they remained unconvinced of the need for a device. Two participants received information from the consultant and ICD or HF specialist nurse, as well as personal sourcing of information. During the individual interviews they were able to recall and reiterate their knowledge and understanding. They also provided accurate details of their cardiac condition, indication, role and function of the device, and discussion of the device benefits and risks. These participants were preoccupied with the negative impact a device might have upon their quality of life, and so the device represented a stressor.

6.3.2 What Influenced The Decision To Accept Or Decline CRMD?

Acceptance and refusal was clearly associated with priorities in terms of quantity versus quality of life. Those who immediately accepted or sourced further information to reinforce their initial decision to accept, prioritised living longer and preventing an early death over possible device complications and harms. In contrast, quality of life and the negative impact of technology was more important to those who declined. Those who hesitated and reconsidered their decision were initially concerned with quality of life and avoiding the imposition of technology upon daily activities. However, once convinced of an unequivocal risk of SCA, preventing an early death rebalanced the decision in favour of accepting the device.

The degree to which participants considered the benefits and potential risks of device therapy also distinguished the types of decision-making. As far as responses show, those who described the *Leap Of Faith* decision-making did not consider the possible harms in any detail in comparison to the other three groups. They were content that the benefit of living longer outweighed any possible risks associated with the device. Whereas, participants in the other 3 decision groups deliberated over the balance of benefit and harm. Ultimately, the pros outweighed the cons for acceptors and vice versa for those who declined. This balance fluctuated for the two who reconsidered their decision until the threat of SCA dominated their thinking. At this stage they accepted a device. Particular concerns for all the participants across the groups were the impact of CRMD upon driving and the device size.

There were mixed responses in terms of confronting the possibility of experiencing shock therapy. Participants who employed *Leap Of Faith* decision-making appeared not to have fully contemplated the potential impact of shock therapy. Recall of discussion was limited and some misunderstanding was evident. Whereas, those who reinforced or reconsidered their decision, expressed a realistic view of what shock therapy may be like. Nevertheless, some participants across these groups also admitted avoiding too much detail and insight of the impact of shock therapy, preferring to address it if and when it happens.

The qualitative interviews provided a deeper understanding about the meaning of the CRMD held by the participants. Those who had either immediately or eventually accepted the device considered it in terms of security. Descriptors used including ‘no brainer’ ‘security blanket’ ‘insurance policy’ ‘own paramedic’ illustrated the level confidence in the device. This was associated with the perception of clinical need in terms of the enhanced risk of SCA and symptom severity. In contrast, CRMD represented a stressor for those who initially and ultimately refused the device. Possible complications and complexities of device therapy and a negative impact upon QOL, outweighed a desire to accept. The participants who declined a device verbalised examples of undesirable, anticipatory anxiety. This was also associated with the perception that symptoms and risk were not indicative of clinical need at that time. Integral to this was the perceived strength of the recommendation by the expert. The approach, tone and words used by the professional were important to the participants and instrumental in their interpretation of the strength of recommendation. Those who adopted the *Leap Of Faith* or *Reinforced Acceptance* decision-making, perceived the recommendation to be strong in contrast to those who declined, for whom it was considered to be weak. The recommendation was perceived to be impartial by the participants who demonstrated *Reconsideration* decision-making. Furthermore, there was a tendency to minimise the likelihood of needing and receiving shock therapy by way of endorsing the decision to accept. Others, particularly those who declined a device had faith in alternative measures to minimise their risk of SCA.

6.3.2.1 The Influence Of Significant Others

Almost all the selected participants were married or had supportive next of kin nearby. The men tended to rely upon spouse opinion and support. In contrast, the women were more likely to confirm their own decision, regardless of whether it agreed with the spouse or not. The data sets corroborated an apparent gender difference in the extent to which they sought information, advice or the opinion of their partner (p=0.04).

There was no significant difference in decisional regret scores across the groups. In addition there was agreement between the low decisional regret scores and the lack of doubt and regret verbalised by the participants.

6.3.3 Contradictions Within The Data Sets

Strand 3 merging also highlighted some discrepancies between the survey and interview responses within the groups. The findings are presented here and discussed in more detail with reference to the literature in Chapter 7. Eighteen out of the twenty participants expressed a range of similar, noteworthy symptoms culminating in the consultation and device recommendation. Yet according to the NYHA self-assessment, there was some discrepancy between the numerical and narrative data. Seventy-six percent who accepted the device considered their symptoms to be marked (Class III). Whereas, despite describing severe symptoms, those who declined a device, scored their symptoms as minimal (Class I) or moderate (Class II). The difference in NYHA scores between those who accepted and those who declined a device was moderately significant ($\chi^2=10.69$; df=6; $p=0.05$).

Despite indicating on the survey, that certain physical, emotional, social and economic benefits and harms of CRMD had been addressed during the consultation, participants who undertook *Leap Of Faith* decision-making were less likely to recall full or accurate details of the conversations, during the interview. Interestingly, when asked, all the participants across the groups stated that they had received the required level of information and that they felt well informed. However, the interview data suggested partial or limited information recall associated with *Leap Of Faith* decision-making.

6.3.4 Revisiting The Conceptual Map

Various decision theories emerging from the literature and scoping review to explain patient treatment decision-making, were combined to form the conceptual map of decision-making. It was designed to provide structure and direction for the development of this mixed methods study. The framework included reference to individual heuristic and systematic information processing, participatory decision making, the impact of match between desired and actual involvement and decisional regret. Monitoring coping styles was included as a possible influence that had not previously been studied in the context of CRMD decision-making. The study also sought to determine what influenced decision-making and the outcome in terms of knowledge acquisition and the actual decision. Some of the findings did not entirely mirror the conceptual map

Participatory decision-making has been conceptualised according to several models revolving around the level of control an individual has over decision-making, ranging from ‘passive’ paternalistic physician control, to ‘active’ informed patient control or shared involvement in information exchange, deliberation and final choice between physician, patient and significant others (Mead et al., 2013; Makoul and Clayman, 2006; Charles et al., 1999). However, the level of participation did not appear to fall neatly in to one or other of the categories described by Charles et al. (1999). Rather, there was a sense that participants felt that they were expected, or allowed to make their own decision based upon information received, either solely from the expert or from additional sources. In terms of participatory decision-making, this study was also concerned with the degree of, and match between desired and actual decisional control perceived by the participant. There was very little difference in the way the participants in this study appeared to judge the desired and actual level of decisional control. The survey data suggested that most participants had favoured and experienced what they considered to be active informed decision making. That is, they made the decision based upon expert and other advice.

Indeed, almost all the participants who adopted *Leap Of Faith* decision-making had indicated on the survey that their desired and actual level of participation was ‘active’. However, the narrative descriptions from the individual interviews did not appear to support this. Although their perception was that they had either independently or collaboratively made the decision, further examination suggests that the expert had often made the final decision to add them to the waiting list. Yet, there was little evidence of total deferral to the consultant (passive) for the decision, as most recalled being asked at some point what they wanted to do. Neither did they actively search for more information, but did consider themselves to have been well informed by the expert. They acknowledged that receipt of expert information alone was sufficient to reinforce their device acceptance. However, they did not appear to be fully informed and therefore could not be described as passive informed.

In contrast, participants who demonstrated *Reinforced Acceptance, Reinforced Refusal or Reconsideration* decision-making also indicated a desire for, and actual active participation on the survey, which was endorsed by similarities in the participant’s interview descriptions of their perceived level of control over the ultimate decision. Twelve participants actively engaged in systematic information processing and subsequently appeared to be well informed to consent or decline. Their decision-making style could be described as active informed. Shared decision making (SDM) in its truest form as described by Lewis et al. (2016) and recommended by NICE (2016) was not evident in this study. However, there was an element of collaboration between some patients and professionals. SDM implies that both parties have something in common that can be shared, whereas collaboration acknowledges that those involved are not necessarily equal but can work together to reach a consensual conclusion (O'Grady and Jadad, 2010). Thus, collective participation among the participants in this study didn’t fit well with the collective participation aspect of the conceptual map.

Lastly, decisional regret has been reported in previous studies. Levels of decisional regret were minimal and did not match any particular type of decision-making. This may have been a consequence of the short time interval between decision and implantation.

6.3.5 Developing A Theoretical Model Of Patient Decision-making For Primary Prevention CRMD

As a result of data immersion, integration and interpretation, a theoretical model, to explain how and what influences adult (>16 years) patients' decision-making to accept or decline primary prevention complex cardiac rhythm management devices (CRMD) in four regional UK implant Centres, was developed (Figure 6.3). The model proposes that certain distinctive and potentially predictive characteristics determine four types of decision-making. Table 6.5 summarises the distinguishing characteristics of the four types of decision-making displayed by the participants in this study. Age, diagnosis, aptitude for HL and a proclivity towards worry and anxiety differed among the types of decision-making. Furthermore, this was associated with a predisposition towards lower or higher monitoring tendencies. Possession of specific attributes may predict an individual’s propensity towards a particular decision-making type and influence the subsequent decision-making journey.

Table 6-6 Characteristics Of Four Types Of Decision-making

	Leap Of Faith	**Reinforced Acceptance**	**Reconsideration**	**Reinforced Refusal**
Age Diagnosis	Older adult IHD	Mid age IHD or NIHD	Mid age IHD or NIHD	Younger adult NIHD or IHD
NYHA Perceived Clinical Need	III High	III High	III High	I / II Low
Emotional Response Anxious	Shock; matter of fact; relief Not anxious	Shock; relief; Anxious +	Matter of fact; open mind Not anxious	Shock; fear; Anxious ++
Educational Level Aptitude for HL Monitoring	< 16 years Low Low	>16 years High High	>16 years High High	>16 years High Highest

The decision-making journey begins when increasing symptom severity leads to a cardiac consultation, which culminates in an often unexpected recommendation for CRMD. Patient’s respond to the severity of their symptoms, the perceived strength of clinical need and the initial recommendation, and their immediate emotional feelings, with an impulsive decision to accept or decline CRMD therapy. The model proposes that patients will adopt alternative decision-making pathways. Various characteristics may predict the decision-making route they take. This will determine the response to heuristic information processing and the likelihood of engaging with systematic information gathering to reinforce or question the initial decision. The type of decision-making subsequently corresponds with differing levels of knowledge recall.

Figure 6-3 Theoretical Model Of Patient Decision-Making For CRMD

Theoretical Model Of Patient Decision-Making For CRMD

Reinforced Acceptance

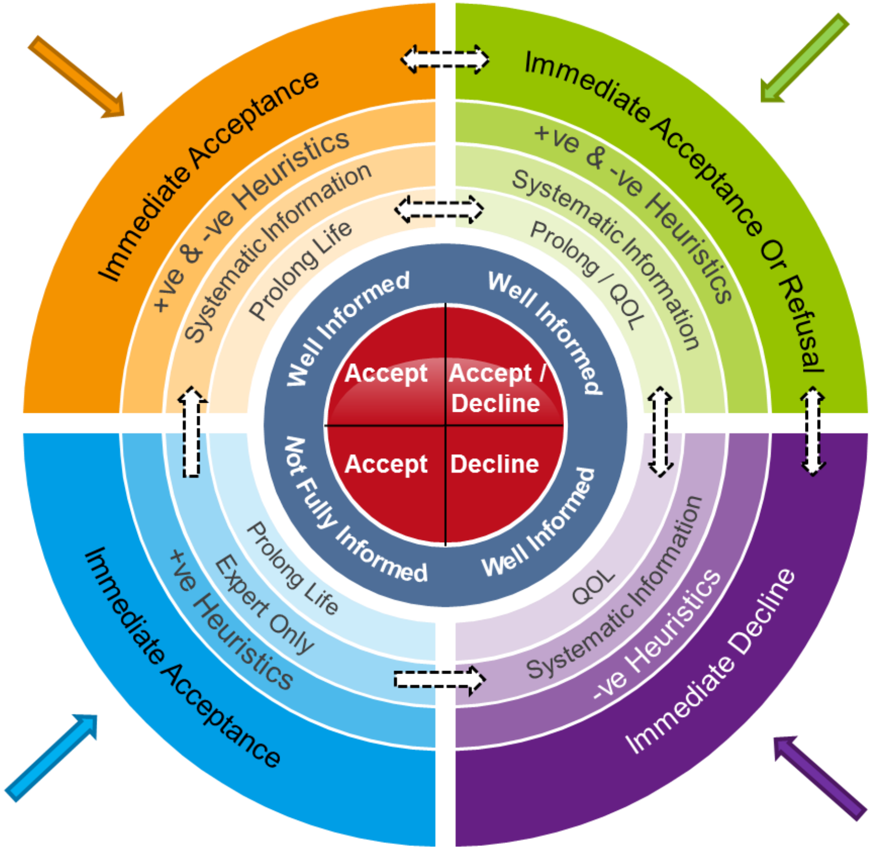
Predictive characteristics:

Mid age
IHD or NIHD
Marked symptoms NYHA III
High perceived need
Shock, some relief
Anxious +
>16 years education
High aptitude for HL
High monitor score

Reconsideration

Predictive characteristics:

Mid age
IHD or NIHD
Marked symptoms NYHA III
Low / high perceived clinical need
Matter of fact, ‘open to suggestion’
Not anxious
>16 years education
High aptitude for HL
High monitor score



Leap Of Faith

Predictive characteristics:

Older age
IHD
Marked symptoms NYHA III
High perceived clinical need
Matter of fact / Relief
Not anxious
<16 years education
Low aptitude for HL
Low monitor score

Reinforced Refusal

Predictive characteristics:

Younger age
NIHD or IHD
Minimal / moderate symptoms NYHA I/II
Low perceived clinical need
Shock & fear
Anxious ++
>16years education
High aptitude for HL
Highest monitor score

6.3.6 Summary Of Strand 3 Findings

In summary, being older, with less than 16 years of formal education, a lower aptitude for HL, low monitoring scores and a more stoic outlook may be predictive of *Leap Of Faith* decision-making. This type of decision-making is associated with a decision to accept CRMD based solely upon a persuasive, positive recommendation from the expert, supported by reference to positive prior experience of self or others and a desire to prevent SCD and prolong life. Information recall is limited and lacks precision among this group. Although not evident in this study, it is feasible that negative framing by the expert and/or recall of unpleasant experiences may provoke a patient to adopt *Leap Of Faith* decision-making and conform to a minimally informed decision to refuse.

Being in the mid-age range, with more than 16 years of formal education, a higher aptitude for HL and high monitoring scores was associated with *Reinforced Acceptance* or *Reconsideration* decision-making. A degree of self-confessed anxiety appears to predict *Reinforced Acceptance* decision-making, whereas a more relaxed outlook was associated with *Reconsideration*. *Reinforced Acceptance* and *Reconsideration* decision-making was influenced by positive and/or negative expert and availability heuristic thinking, but supplemented by systematic information processing. A desire to prolong life was associated with *Reinforced Acceptance* decision-making. Whereas, *Reconsideration* decision-making was associated with deliberation of the benefits and harms allowing participants to reconsider their initial decision and change their mind. Whether the initial decision is reinforced or reconsidered, participants who adopt these decision-making styles appear to be well informed

In contrast, *Reinforced Refusal* decision-making was associated with younger adults, with more than 16 years of formal education, a higher aptitude for HL, the highest monitoring scores and self-reported evidence of heightened anxiety states. The strength and confidence in expert opinion was weakest for this group and reference to availability heuristics tended to present a negative bias. Systematic information processing serves to reinforce the initial doubt and prioritising quality of life over longevity influences a decision to decline. Participants who adopt this approach are also well informed.

However, the model is not designed to be static, but a dynamic and fluid representation of how patients may approach and make decisions regarding primary prevention CRMD. Arrows within the model illustrate how individuals may start their decision journey, but with different experiences could divert on to an alternative route. For example, having adopted *Leap Of Fait*h decision-making to accept a device on expert recommendation, unplanned exposure to further information may deflect someone towards a more informed decision to accept or decline a device. Similarly a notable change in perceived symptom severity and clinical need, or change in desire for quantity or quality of life may affect the decision path taken.

Although data integration has verified the decision-making types, the model at this stage is only representative of the experience of twenty participants. Further empirical, theoretical testing is required in anticipation that the generalisability of the model to a wider audience may be exploited.

Chapter 7 draws upon the study findings from Strand 1 (Chaper 4), Strand 2 (Chapter 5) and Strand 3 (Chapter 6), to present a detailed discussion of the proposed theoretical model of patient decision-making for CRMD, within the context of contemporary literature and practice. The strengths and weaknesses of the study design are considered and researcher reflection and reflexivity are discussed. Chapter 7 concludes this thesis with 5 key messages, several implications for practice and recommendations for future research.

Chapter 7 Discussion, Recommendations And Conclusion

7.1 Introduction

Chapter 7 presents a detailed discussion of the cumulative findings from Strand 1, 2 and 3 of this thesis. The aim of this thesis was to explore how and why patients make decisions regarding primary prevention CRMD therapy. The research question posed was;

> **‘What influences adult patients' decision-making in accepting or declining primary prevention complex cardiac rhythm management devices (CRMD)?’**

This empirical inquiry has expanded the literature around the decision-making behaviour of patients, revealing similarities and differences with findings from the scoping review and contemporary decision-making literature. It has provided detailed insight into the way adult patients requiring cardiac devices approach decision-making, and the factors that appear to influence that approach, and the decision to accept or decline CRMD. These novel findings are described as a decision-making journey. Various theories, models and typologies of patient treatment decision-making exist in the literature. They have focused upon the way individuals internalise their decision-making and / or levels of involvement in collective participation (Garrett et al., 2019; Flynn et al., 2006). This chapter aims to position the study findings and proposed theoretical model within the context of contemporary literature and practice.

An overview of the theoretical model is given. The discussion is then divided into sections in order to consider each element of the theoretical model in detail. First, the process of primary appraisal leading to an immediate decision to accept or decline a device, will be discussed. Then a discursive analysis of the typologies of decision-making in terms of the deliberative route taken to reach a final decision will follow. A detailed analysis of the predictive characteristics and influences that appear to induce an individual to adopt one or another decision-making route, and the decision to accept or refuse a device, is presented. Finally, the impact of decision-making upon the levels of knowledge acquisition, recall and informed consent among the participants will be considered. Reference to researcher reflection, reflexivity and quality issues such as validity, credibility and transparency will be presented. The study strengths and weaknesses, implications for clinical practice and recommendations for future research are also considered.

7.2 A Theoretical Model For Decision-making

The process of decision-making appeared to be triggered by the apparent shock produced by the recommendation for a primary CRD, and the sudden realisation of the increased risk of SCA. Decision-making appeared to occur in two distinct phases and these are located in the theoretical model of patient decision-making for CRMD (Figure 6.3). Uniquely, this study has identified four types of decision-making adopted by patients offered a cardiac device. They are described in this model as *Leap Of Faith*, *Reinforced Acceptance*, *Reinforced Refusal* or *Reconsideration*. The model illustrates the interplay between various complex influences, and the different types of decision-making employed in response to the recommendation.

What became apparent was that the expert's recommendation for primary CRMD induced intuitive, 'thinking fast' (heuristic) processes. The primary appraisal of the situation was dominated by heuristic thinking, resulting in an immediate, impulsive and emotionally laden decision to accept or decline a device, by everyone at the point of the recommendation. The decision remained resolute for most participants. The outer ring of the theoretical model represents the immediate decision (Figure 6.3). This study identified a range of contextual factors that appeared to influence the immediate decision to accept or refuse a device. They were the degree of positivity and/or negativity assigned to heuristic thinking, the perceived symptom severity, clinical need and strength of recommendation. Personal goals in terms of quantity or quality of life were also instrumental in the participants' decision-making.

Time then allowed a period of deliberation to ensue culminating in a final decision. The secondary appraisal involved an element of 'thinking slow' (systematic) processes. This presented the opportunity for further information gathering and processing, in order to weigh up the pros and cons of accepting and refusing device therapy. The inner rings of the theoretical model represent the journey towards the final decision (Figure 6.3). Thus, the findings from this study support the dual-process model of individual decision-making described by Epstein, R. (2013), Kahneman (2011), (Chen, S. and Chaiken, 1999) and others.

The theoretical model proposes that the four types of decision-making are distinguished by various socio-demographic and situational characteristics. A statistically significant association between type of decision-making and age, cardiac condition, years of formal education, aptitude for health literacy (HL), monitoring scores and a propensity to worry, was revealed in this study. These characteristics could predict the alternate decision-making journey an individual might take. Previous studies have suggested that women may be more likely to engage with systematic information gathering (Chung et al., 2012; Flynn et al., 2006), however this was not evident in this study. A dearth of literature exists regarding the potential influence of race, religion and cultural difference upon decision-making. Exploration of the potential impact of culture is important because current decision theory may be more applicable to Western individualist cultures that encourage greater confidence in independent decision-making. This may not fit as well with group orientated cultures, such as Asian communities (Hawley and Morris, 2017). However, the intention to explore the decision-making experience among British white, black and minority ethnic (BME) groups was frustrated by the lack of recruitment of representative participants. Therefore, the potential influence of race, religion and cultural differences could not be evaluated.

The type of decision-making mattered because it influenced how well informed the participants were. The manner in which participants engaged in information processing, the degree of participation in decision-making and the level and accuracy of knowledge acquisition and information recall characterised the alternate decision-making journeys. This in turn determined the extent to which patients appeared to be informed to give consent. The impact of desired and actual decisional control and a potential mismatch were not significant and levels of reported decisional regret were minimal.

7.3 Setting the Scene

In order to fully understand the personal meaning of the patients' decision-making experience, it is important to position the decision-making journey in context. Although a few participants had some prior awareness of the potential for CRMD recommendation, this was not so for most. Also, those with inherited cardiac conditions (ICC) who were vaguely aware that CRMD may become a treatment option, had '*parked*' the idea out of immediate consciousness. Therefore, the unexpected revelation that their cardiac condition had increased their risk of an early sudden death, enough to meet the criteria for primary prevention CRMD, was met with shock, surprise or fear for most. Similar reactions which had triggered decision-making were described in the scoping review (Groarke et al., 2012; Carroll et al., 2011; Gal et al., 2011; Agard et al., 2007).

7.3.1 Nothing More Certain Than Death And Uncertainty

The seriousness of the ‘life or death’ event became evident. The fear of death is a universal human phenomenon, and confronting it presents a formidable human concern affected by personal experiences and socio-cultural beliefs (Lehto and Stein, 2009). Although mortality represents one of very few certainties in life, most individuals will consider it rarely, unless they suffer with death anxiety (Sharif Nia et al., 2016). Noah and Reiche-Graefe (2019) suggest that ‘*mortality-induced vulnerability*’ p561 prompts most people to avoid acknowledging mortality much of the time. Instead, attention focuses upon surviving and thriving and ‘*an illusorily endless, in-tandem accrual of both quantity and quality of future life*’ p562 (Noah and Reiche-Graefe, 2019). However, an intermittent sense of the fragility of existence and inevitable mortality may be prompted by the death of others or a personal close encounter. A recommendation for CRMD signifies an increased, albeit uncertain and unquantifiable, greater than average risk of SCD. In response to the realisation and infallibility of death, ‘*dis-illusion’* is said to ensue (Noah and Reiche-Graefe, 2019). The balance of ‘*quantity/surviving and quality/thriving’* life may become altered, uncertain, antagonistic or even mutually exclusive (Noah and Reiche-Graefe, 2019). Inevitably, the recommendation compelled the participants to contemplate their own mortality and accept the increased uncertainty regarding their future as a fait accompli. Where they were previously subject to the threat of terminal illness and predictable death or sudden death from disease, accident or injury as others, CRMD appeared to signify a third reality for this group. That is, the potential for technology to abort a sudden death. Thus, individuals were faced with the fact that technology could place them in a unique but potentially threatened position. This in itself presented a major stressor which undoubtedly influenced decision-making among this group of patients.

Illness that represents a fundamental threat to survival and well-being invariably elicits a range of affective experiences, such as anxiety, fear, anger and depression (Kiviniemi et al., 2018). Vivid recollections of the impact of the recommendation by the participants suggested that the recommendation had elicited feelings of stress and anxiety. In addition, unlike treatment decision-making for life threatening cancer, CRMD therapy represents a largely unknown, unheard of treatment. Therefore, a general lack of knowledge and understanding to underpin decision-making was implicit. Furthermore, the quantifiable evidence to support the potential outcomes with and without a device remains equivocal. This creates a backdrop of uncertainty, ambiguity and insufficiency of pertinent, individualised information, available to the healthcare professional (HCP) to guide the patient. Therefore, the combination of an unknown yet unavoidable degree of clinical uncertainty related to the cardiac condition, benefits and risks of CRMD, and non-clinical uncertainties such as personal experience and preferences, added to the complexity of decision making.

Within the current healthcare system which embodies respect for the right of individuals with capacity to make autonomous, informed and un-coerced decisions, participants were required to make a decision regarding acceptance or refusal of CRMD therapy. They were expected to search for and assimilate new and complicated information, in order to weigh up the potential positive and negative outcomes, and make a decision regarding CRMD technology. The requirement to make a decision under such conditions may represent an additional 'acquired' stressor for some (Janis and Mann, 1977). Therefore, the shock, threat and stress associated with their cardiac condition, sudden death and device therapy was compounded by the stress of having to reach a decision.

In response to the stress of illness and threat, individuals are said to engage in cognitive, problem-focused systems that instigate the motivation to act in a positive, effective manner, and emotion-focused strategies aimed at managing and reducing the emotional distress (Luo and Yu, 2015; Cameron, 2003). Although the literature is scarce, it is becoming increasingly evident that emotions such as stress and anxiety are a powerful and dominant driver in most decision-making (Ferrer and Mendes, 2018; Lerner et al., 2015). Various physiological mechanisms and psycho-social theories have been posited as explanation for decision-making under duress. Physiologically, the immediate experience of shock invoked by CRMD recommendation may have instigated automatic, defensive reactions mediated by the amygdala. This can interfere with cognitive function and lead to a 'bottom up' influence on decision-making (Luo and Yu, 2015). The closer the proximity or imminence of threat and the more self-relevant the stimulus, the more emotion is likely to be involved in the decision (Luo and Yu, 2015). Therefore, the intensity of emotion impelled by feelings of shock and a heightened perception of risk of SCA may have influenced an initial, emotionally laden response. Janis and Mann (1977) had asserted that under conditions of stress, non-adaptive hypervigilance leads to a deterioration in thinking and deliberation and hasty impulsive acceptance of a decision without an adequate search for information and full deliberation. High levels of stress have been associated with various non-adaptive, emotion-focused decision strategies in cancer studies (Hollen, 1994; White et al., 1994; Pierce, 1993; Terry, 1992). In this study, hypervigilant decision-making typified the way that all the participants arrived at the initial impulsive decision to accept or decline a device.

7.4 The Immediate Decision - ‘Thinking Fast’

Kahneman (2011) has long argued and illustrated that individuals will employ ‘thinking fast and slow’ strategies in decision-making. Primary appraisal was characterised by thinking fast for all the participants. That is, they were shocked by the recommendation, listened to the expert and made an immediate impulsive decision. This was to accept a device for some, but not for others. The participants who engaged with *Leap Of Faith* or *Reinforced Acceptance* decision-making readily accepted the experts recommendation to receive a device. Whereas, those who employed *Reinforced Refusal* or *Reconsideration* did not. Either way, it was important to know what had influenced the immediate decision, because the decision remained resolute for the majority of the participants.

There was a statistically significant association between device refusal and being younger, having an inherited cardiac condition (ICC) and the highest monitoring scores. Whereas, device acceptance or refusal did not appear to be influenced by any other socio-demographic characteristics. Indeed, a larger survey study of 295 ICD recipients by Green et al. (2016), did not identify any significant difference in gender, race, education, marital status or co-morbidities between device acceptors and decliners.

Heuristic information processing, or cognitive shortcuts thought to provide a means for thinking fast were discussed in detail in Chapter 1. Instances of heuristic thinking were evident among all the CRMD participants. Whilst not an unexpected finding, this study did reveal greater insight in to the effect of heuristic thinking upon decision-making than previous studies. Heuristics influenced the way the participants approached the immediate decision and the deliberative step in decision-making. Although heuristics are said to speed up the decision-making process, this may be at the expense of introducing predictable and systematic cognitive bias and error, leading to deficient judgements (Steginga and Occhipinti, 2004; Kahneman and Tversky, 1996). What is evident through this study is that the positive and negative nature of heuristics, the perceived strength of recommendation, severity of symptoms, clinical need for a device, and an evaluation of ‘quantity/surviving’ and ‘quality/thriving’ were instrumental in determining immediate acceptance or refusal.

7.4.1 The Positivity And Negativity Effect

Without exception, everyone had valued the express opinion of the cardiologist(s), ICD and HF specialist nurses. The inevitable informational asymmetry and limitations in patient knowledge, cognition, foresight, and experience of difficult decision-making in the face of uncertainty and fear, validates the importance and unavoidability of the expert opinion heuristic (Steginga and Occhipinti, 2004; Chaiken et al., 1989). Despite some criticism levelled at the use of the term ‘expert opinion heuristic’ by Hamm (2004), in this study, expert opinion appeared to be a highly influential element of the immediate decision and distinguished the types of decision-making. The participants were explicit in the way they described the level of reliance and acceptance of information gleaned from the consultant (and / or nurse). The degree of positivity and negativity assigned to expert opinion appeared to affect the patients’ decision approach and the outcome to accept or decline CRMD.

The ‘expert opinion’ heuristic is dependent upon the level of trust in the expert, which in turn equates to the perceived strength of recommendation (Marewski and Gigerenzer, 2012). In this study, the healthcare practitioners (HCP) approach was important to all the participants. Some preferred the straight, blunt and to the point approach, others preferred a softer, more friendly and approachable style. Either way all considered the approach they were faced with to be the relevant one. The participants who expressed high levels of faith, trust and confidence in the HCP, and whose interactive style suited them, were more likely to accept expert opinion without question. Thus, expert opinion couched in positive terms was associated with immediate, unquestioned device acceptance and *Leap Of Faith* decision-making. Several studies have observed the influence of the professional ‘halo effect’ upon decision-making, particularly when the expert was viewed by the patient in positive terms, related to trust, respect or affection (Garrett et al., 2019; Gainer et al., 2017; Matlock et al., 2017). An over confidence in the accuracy and reliability of information gathered heuristically can lead to decisions based upon ‘gut feeling’ or inappropriate past experience. This was particularly evident among patients who frequently and emphatically mentioned their trust and faith in the expert and significant others and adopted *Leap Of Faith* decision-making. These participants also expressed a sense of luck, praise and gratitude towards healthcare professionals (often nurses) and extolled the virtue of the NHS institution. It is feasible that an element of the Hawthorne effect could be attributed to some exaggeration of the observed influence of the professional ‘halo effect’ in this study. The consequence of research participation upon the behaviours of the participants remains undisputed (McCambridge et al., 2014). However, McCambridge et al. (2014) concluded that the pre-requisite context for and the mechanism and magnitude of the Hawthorne effect remained unclear. It is therefore difficult to assign the extent to which altered behaviours may have biased the findings in this study. That said, reference was made to historical experiences and expectations of a paternalistic model of healthcare espoused to in the early to mid-20th century NHS. This may have accentuated the evident trust, faith and confidence in the expert's advice, leaving further possibilities unchallenged. Some participants, either had no desire or motivation for, or actively avoided gathering information from other sources. Thus, heuristic information processing dominated the immediate decision, and the 'deliberative' phase of decision-making only extended as far as recall of the experts advice to reinforce the decision to accept. Corresponding behaviours were reported by Lucas (2012), Smith, S. et al. (2009) and others in the scoping review.

When expert opinion was important, but not unreservedly so *Reinforced Acceptance* or *Reconsideration* decision-making ensued. The degree of trust and confidence in expert opinion was evident but not as emphatic and did extend to a degree of reticence and questioning of expert authority. The scoping review revealed an association between lack of trust in the expert and passive referral to significant others (Ottenberg et al., 2014; Yuhas et al., 2012; Carroll et al., 2011; Gal et al., 2011). This was not evident in this study. The participants who expressed some doubt regarding trust and faith in the HCP's, were more likely to engage with further active information gathering and processing to inform their decision. It has been suggested that having less trust in authorities equates with greater perceived risks of technology than those with more trust and this could have a direct impact upon the decision maker (Slovic, 1996). This could explain a desire to explore other sources of information.

In contrast, when there was some scepticism regarding expert opinion, it was disregarded and proceeded by *Reinforced Refusal* decision-making. The participants who declined a device valued the expert's opinion but perceived the attitude of clinicians towards a device to be more nonchalant. They were not persuaded to adopt the expert's advice, and pursued systematic information gathering to reinforce their decision to decline the device against the expert's recommendation. This supports similar findings in the scoping review. Therefore, whether it be termed expert-influence or expert-opinion heuristic, it was possible that the degree of trust in the doctor is the heuristic that may lead to a biased decision.

The immediate decision also appeared to have been influenced by referral to prior knowledge of defibrillators gleaned from media sources such as TV or the experiences of significant others. This is described as ‘availability heuristics’ (Tversky and Kahneman, 1974). The subjective ease with which experiences are recalled, which has been linked to the frequency of occurrence, is said to influence the degree of emphasis and reliance upon availability heuristics (Kahneman and Tversky, 1996). As CRMD represents a relatively new, unique and sophisticated technology, having any prior experience is likely to be infrequent and knowledge minimal. Any prior knowledge of it, whether TV and media or family and friends is likely to be recalled as a consequence of the magnitude, similarity and relevance to their own situation. Decisions which are made upon available, though not necessarily reliable, accurate or relevant sources of influential information, or the vicarious experience of others may also represent a positive or negative bias (Mead et al., 2013; Steenland et al., 2011; Kahneman and Tversky, 1996).

The ‘positivity effect’ has a tendency to enhance attention upon positive information among older adults compared with greater emphasis upon negativity by younger decision-makers (Carstensen et al., 2011; Mather and Carstensen, 2005). Furthermore, Finucane et al. (2000) suggested that when positive affective feelings are aroused by a choice situation, individuals are more likely to judge the benefits as high and risks as low. Consequently, positive feelings generated by the positive opinion assigned to the device by others were associated with acceptance. In a recent study of 48 primary ICD recipients, Matlock et al. (2017) revealed similar instances where availability heuristics appeared to influence the patients’ perception of how likely they may be to experience a SCA. This in turn influenced a decision to accept a device. The uncritical acceptance of suggestions that confirm the beliefs they already held, and an exaggerated perception of the likelihood that an improbable or extreme event might occur has been described as ‘confirmation bias’ (Kahneman, 2011; Tversky and Kahneman, 1974). However, the terms pacemaker, ICD and CRT-D are often used interchangeably in clinical practice, and this could lead to some confusion and misrepresentation. Further questioning revealed that some participants reflections upon how well a significant other appeared to be with their device, had been based upon the incorrect assumption that the device was a defibrillator. Therefore, the use of alternative terminology was potentially misleading and may compound the positivity bias effect.

In contrast, negative feelings aroused regarding CRMD was associated with device refusal. For example, any inference in TV hospital dramas and social media coverage are usually concerned with external defibrillation and not directly applicable to ICD implantation. Yet, reference to this created unrealistic imagery and ideation in terms of device size and shock therapy among some of the participants. This represented a negative availability heuristic and was associated with device refusal. Matlock et al. (2017) also found that recall of device complications or unpleasant effects were associated with device refusal.

7.4.2 The Severity Of Symptoms And Strength Of Perceived Need

The impact of the participants' symptoms upon their physical, emotional and social wellbeing should not be underestimated. It was conceivable that the severity of symptoms would be crucial in determining their decision. The relevance of symptom severity and perception of clinical need was not entirely clear in the scoping review. The review did find an association between the perception of severe symptoms and clinical need and immediate unquestioning device acceptance (Lucas, 2012; Carroll et al., 2011; Gal et al., 2011; Matlock et al., 2010; Agard et al., 2007). This was evident in this study (*Leap Of Faith* decision-making). Furthermore, and consistent with Yuhas et al. (2012) and Carroll et al. (2011), this study also confirmed that individuals with severe symptoms tend to engage in more active decision-making to support device acceptance (*Reinforced Acceptance* and *Reconsideration* decision-making). Those who accepted the device tended to view their cardiac condition as severe and had a stronger appreciation of their personal risk of SCA. Device acceptance reflected the belief that it could prolong life and / or improve QOL. This is consistent with Matlock et al. (2017) who concluded that patients who face a life threatening condition, and judge their health state to be poor, may be more pre-occupied with the immediate threat of death and so assign a higher level of importance to CRMD.

While the scoping review suggested that some people with minimal symptoms, also perceived a need and so accept a device without question (Yuhas et al., 2012; Carroll et al., 2011; Matlock et al., 2011), this was not evident in this study. In contrast, an insufficient perception of severity of symptoms and a minimised belief in the risk of SCA was associated with *Reinforced Refusal* decision-making. Those who declined a device in this study, used similar language to describe the severity of symptoms experienced but classified them as minimal to moderate on the NYHA scale. Therefore, it was not the experience of symptoms that mattered but rather the extent to which they believed it affected their daily lives. This signified a diminished perception of clinical need for a device also reported in the scoping review. It is therefore an individual's perception of their 'state' or condition, described as 'state dependence' that may influence their experience and decisions (Matlock et al., 2017). Those who declined a device displayed an element of ‘optimism bias’ which is defined as *‘the difference between a person's expectation and the outcome that follows. If expectations are better than reality, the bias is optimistic’* p.941 (Sarot, 2011). Optimism bias is common and gender, age and ethnically neutral (O'Sullivan, 2015). Matlock et al. (2017) described optimism bias among young decliners in their study who perceived themselves to be healthier and less likely to need a device than others. It has been suggested that it may lead to poor decisions such as ignoring or evading health matters in the belief that the outcome will be alright. Indeed, in this study people who declined the device may have disregarded expert recommendation, as they appeared to regard their symptom severity and clinical need to be lower than those who accept.

The discrepancy between narrative and numerical judgement of symptom severity was not helpful in determining the effect of symptomatology upon perception of need. For some, the increasing incidence of symptoms may be associated with a heightened perception of risk. Whereas, despite similar severity the infrequency of symptoms may have persuaded others to maintain personal control over their condition rather than accede to technology. The length of time experiencing symptoms may also alter the perception of severity and tolerability. Further examination of the impact of symptom severity upon decision making and the usefulness of the NYHA scale as an assessment tool may clarify this.

7.4.3 The Balance Of ‘Quantity / Surviving’ And ‘Quality / Thriving’

The perception of need and risk of SCA translated in to an immediate evaluation of the participant's personal goals. The balance between quantity versus quality of life was crucial to the decision. In a previous study involving primary and secondary device recipients, reasons for accepting a device were reported as improved quality of life (29%), prolonging life (23%), doctor knows best (16%) and no choice (17%) (Green et al., 2016). Staying alive was considered important regardless of the ICD decision for 10 men (Carroll et al., 2018). In this study, participants focused upon prolonging life, quality of life or both.

When the fear of SCA became foremost in their thinking, prolonging life or both was the priority for patients who accepted a device. *Leap Of Faith* decision-making was particularly associated with prolonging life or both. Green et al. (2015) describe the societal bias towards prolonging life and avoiding death reported among 44 older ICD recipients (Mean age >77 years). However, focus upon the pros with minimal reference to possible cons represented *Leap Of Faith* decision-making. The pros signified an unquestionable, ‘*better to have than not’* attitude towards device implantation. Yet, the survival benefit, particularly in the first post implant year may be diminished in some older adults (Swindle et al., 2010). Furthermore, older device recipients are as likely to experience peri-post operative complications as others and may face the challenges associated with deactivation sooner.

Prolonging life was also a priority for those who engaged with *Reinforced Acceptance*, however they were more vigilant in their consideration of the pros with the cons. Participants who accepted a device, described the decision as a ‘*no brainer’* based upon device capacity to provide ‘*additional protection’* and prolong life. They also communicated a desire for extra vigilant protection, variously describing the device in terms of a *‘security blanket’*, *safety net’*, *‘reassurance*’, ‘*back up’, ‘insurance policy’* and ‘*peace of mind’*. The same descriptors were noted by Gal et al. (2011) and Agard et al. (2007). Analogies were often used to explain their view, referring especially to cars, spare engines, new starter motors, MOT’s and ‘*tune ups’* or *‘little bit of magic’, ‘wizardry’ ‘belt and braces’* and *‘internal paramedic’.* Similar expressions of the faith, hope and trust in device capability, described in the literature as the ‘technical halo effect’ were also reported by Matlock et al. (2017) and Green et al. (2015).

Balancing views about the quantity and quality of life played a greater part in decision-making among those who were more hesitant, leading to a change of mind. However, once the threat of SCA became unequivocal, the decision to accept was made. Those who stated a desire to prolong and improve their lives usually had a CRT-D, or if not referred to the opportunity for more aggressive pharmacological measures with an ICD. In contrast, quality of life was most important for those who refused a device. This group considered device therapy to be an extreme, unnecessary measure, and diminished the perception of risk and need. They dwelled upon the potential adverse effects of device therapy upon their quality of life and reported experiencing anticipatory anxiety related to shock therapy. This reflects similar findings by Ottenberg et al. (2014), Singh, N. et al. (2012) and Carroll et al. (2011). It is noteworthy that, as the youngest participants, the NIHD diagnosis confers more uncertainty in terms of device benefit and they are more likely to experience the negative consequences and risks of device therapy. That said, in the event of SCA, they are more likely to survive with shock therapy than those with IHD. For those who declined, disease progression as an indication of increased risk of SCA may provide a categorical and more persuasive need for device implant.

In this study, most did recognise the burden of the one month driving ban post implant, feared receiving a shock while driving, and the threat of loss of licence was a significant issue for the majority of the participants. Despite this, the need to give up heavy machinery or welding work, and concerns regarding device size, those who prioritised the security afforded by the ICD accepted implantation. In contrast, the potential loss of driving freedom was sufficient to cause one patient to consider refusal and another to decline entirely. That said, it did not discriminate between the decision-making types but rather represented a common issue. Similarly, device size worried participants across the types. The subcutaneous system was associated with fewer complications than the transvenous device and did represent a potential tipping point for those who initially refused. However, less consideration was given to the limited set of treatments available with the subcutaneous option. Shock therapy was also an issue for most of the participants. Those who accepted the device appeared to minimise the impact or likelihood of receiving shock therapy. Whereas, recognition of anticipatory anxiety related to shock therapy, was an absolute factor in refusal for one participant.

In summary, the immediate response from all the participants reflects the uncertainty and ambiguous nature of primary CRMD recommendation prompting them to employ intuitive, fast decision-making that appeared to be emotionally laden. A positive view of the expert and availability heuristics, in combination with a marked self-assessment of symptom severity, translated in to what was perceived to be a strong recommendation that could not be ignored. Thus, *Leap Of Faith* decision-making was shaped by heuristic thinking that was interpreted in a positive light. Participants who adopted *Reinforced Acceptance* or *Reconsideration* decision-making referred to positive and negative expert and availability heuristics and a marked self-assessment of symptom severity. The perception of clinical need for a device was generally construed to be a reasonable requirement rather than essential necessity. The balance of quantity and quality of life determined acceptance or refusal respectively. In contrast, examples of expert and availability heuristics that were negatively biased, translated into a recommendation that was considered to be weak and disproportionate to the perceived need. Despite describing what appeared to be significant symptoms, those who declined a device scored their symptoms as minimal or moderate. This culminated in *Reinforced Refusal* decision-making. Thus, the immediate hypervigilant decision based upon heuristics represented abstract thinking, which required translation into concrete and context specific choices for all.

7.5 The Deliberative Phase - Thinking Slow

Having made a ‘fast’, impulsive decision based upon available, accessible, comprehensible knowledge gleaned thus far from expert and availability heuristic thinking, the participants entered a more considered decision-making phase, driven by the threat of a higher than average risk of SCA. The inner rings of the theoretical model represent the journey towards the final decision (Figure 6.3). The deliberative phase describes how and why patients gathered and processed further information to make sense of, and endorse their initial decision. A distinction between decision approaches based upon the level of engagement with systematic information processing was evident in the scoping review (Chan et al., 2016; Groarke et al., 2012; Carroll et al., 2011; Matlock et al., 2010). While the distinction between passive and active decision-making was evident, this study identified a new set of typologies based upon engagement with heuristic-systematic information processing.

Leap Of Faith decision-making did not engage with further information gathering which resembled passive decision-making. These findings represent a slight decrease in sole reliance upon heuristic decision-making since the studies by Groarke et al. (2012) and Matlock et al. (2010). This may be a reflection of the increasing emphasis upon informed consent in current healthcare and / or the ease of access, and growing reliance upon online information sources. Sole reliance upon affective, heuristic decision-making was associated with low level recall of information and understanding acquired for informed consent. Janis and Mann (1977) described failure to seek or appraise further information regarding choice and alternative options as a non-adaptive, inferior decision strategy which resulted in poor decision-making.

In contrast, intuition based ‘thinking fast’ was followed by ‘thinking slow’ systematic information gathering and processing among some participants (Kahneman, 2011). This phase presented the opportunity to dwell upon the decision and gather other sources of information to reinforce or undermine initial thoughts among the participants. That is, deliberative processes produce a slower rational response that may correspond or antagonise the initial intuitive decision (Kahneman, 2011). Doubting or ‘unbelieving’ is said to occur as a consequence of conscious activation of the slow, effortful, analytic information gathering of ‘system 2’ (Kahneman, 2011; Gilbert et al., 1993). Systematic information gathering and processing presented the opportunity to weigh up the balance of perceived benefits and risks with and without device therapy. Janis and Mann (1977) alleged that this type of adaptive vigilant decision-making, that promoted information processing, would lead to a high quality decision (Janis and

Mann, 1977). This was a component of *Reinforced Acceptance*, *Reinforced Refusal* and *Reconsideration* akin to active decision-making, and was associated with a higher level of information recall and understanding.

This study sought to explain the disparity in information seeking behaviour among the participants. The complexity, unfamiliarity, ambiguity and uncertainty associated with life threatening health issues and treatment decisions such as CRMD, may predict a tendency towards heuristic rather than systematic processing. Cognitive reduction occurs when cognitive capacity is weak due to either information ambiguity or time constraints (Luo and Yu, 2015). Therefore, deliberation is more likely to emphasise unrelated or easily accessible and available, emotionally based heuristic information which could lead to sub-optimal decision-making (Luo and Yu, 2015). However, the participants were exposed to equally complex information. Furthermore, unlike a recommendation for secondary prevention which usually requires an immediate action, a proposal for a primary preventative device affords more time for deliberation. The participants in this study all acknowledged having time for decisional deliberation. Therefore, in the absence of time constraints, there was an equal opportunity to engage cognitive processes. Yet this was not evident in all cases in this study.

The types of decision-making were characterised by the degree to which patients engaged with affective, heuristic thinking and cognitive, systematic information processing to support the final decision. While decision theories provide an explanation of how patients may make treatment decisions, they do not explain why or what influences their decision approach particularly well. Janis and Mann's (1977) Decisional Conflict Theory (DCT) has been criticised for adopting a process focused view that largely fails to acknowledge the influence of various personal, situational, transactional and temporal antecedents upon the style of decision-making (Lazarus and Folkman, 1984). The DCT model does not account for the complexity of the individual situation, and failed to factor in what the current situation might mean to the individual in terms of benefits, harms and goals that influence coping patterns and decision outcomes (Balneaves and Long, 1999). Luo and Yu (2015) also argue that dual-process models remain conceptually unclear, that emphasis upon the dichotomy of emotion and cognition is oversimplified, and that the interplay and dominance of one system over the other is not sufficiently well developed to explain the complexities and nuance of individual decision-making. If targeted support mechanisms are to be developed to ensure that patients are well informed, regardless of the type of decision-making they employ, further analysis of factors that affect emotional and cognitive processing is required. This study has identified different types of decision-making, providing a novel perspective that goes some way to overcoming some of the challenges with decision-making theory. Several features associated with each type of decision-making emerged from the Strand 1, 2 and 3 data sets. The theoretical model proposed, includes reference to certain characteristics that appeared to be instrumental in determining the extent of emotional and cognitive information processing during the deliberative phase of decision-making.

7.5.1 Unpicking The Impact Of Age

Age and cardiac condition appeared to distinguish group participants. Older adult is currently considered to be >65 years (World Health Organisation, (WHO). 2018; Gorman, 1999). Although not exclusive to older adults, mortality from IHD is approximately 5.5 times higher in the over 65 than under 65 year old population in the UK (BHF., 2019). Therefore, the rate of IHD among this group is likely to be age related. Being older (M=65.75 years), being more likely to have IHD, and the perception of a marked symptom severity characterised *Leap Of Faith* decision-making. On the contrary, as invasive and surgical procedures have advanced in recent years, young people with inherited cardiac conditions (ICC) are living longer. Consequently, CRMD recommendation for ICC occurs in young to middle aged adults. *Reinforced Refusal* decision-making was associated with younger participants, with ICC who considered the severity of symptoms to be minimal or moderate. This study suggests that age is a major factor in the type of decision-making for CRMD

Hearing, learning and memory deficits associated with increasing age are frequently linked to a significant decline in cognitive ability, including verbal and spatial working memory, numeracy, speed of processing, reasoning and problem solving (Zamora and Clingerman, 2011; Donelle et al., 2007; Salthouse, 1996; Park et al., 1996). As a consequence of reduced cognitive deliberation, an enhanced emphasis upon emotional outcomes and goals, and a reliance upon heuristic processing to inform decision-making among older adults, is frequently referred to in the literature (Peters et al., 2007). Older age was associated with ‘passive’ decision-making tendencies in the scoping review (Hauptman et al., 2013; Lucas, 2012). Garrett et al. (2019) explored decision-making among 13 late stage melanoma patients and found similar differences in the extent to which they engaged individually and collectively with the decision. They also describe a group of patients who relied upon the expert’s opinion and considered their role in decision-making to be limited, as ‘reliant outsiders’. Reliant outsiders were comparatively older with a mean age of 62 years, were more likely to be male (1 woman of 5), and reported lower level education (none had degree) than other patients studied (Garrett et al., 2019). This study did not identify a gender difference, however the notion of ‘reliant outsiders’ resonates with *Leap Of Faith* decision-making.

Mikels et al. (2013) concluded that an age related reliance upon heuristics was due to a tendency to attach greater significance to emotional information than younger people, rather than a function of declining cognitive capacity. Furthermore, confirmation bias is said to occur as a consequence of the influence of desire over belief. The dominant desire to live longer may transcend the need for further information and so avert activation of system 2. Thus, information which confirms the view is embraced at the expense of contradictory evidence which may be ignored or rejected. Consequently, participants who employed *Leap Of Faith* decision-making, did not consider the potential risks of CRMD implantation in any detail. In fact, there was no evidence of alternative information gathering with *Leap Of Faith* decision-making. Participants were content with information and advice given and so had no requirement to systematically gather other sources of information.

The use of affective information may also be enhanced as a result of age related changes in social goals. As individuals approach later life, reliance upon social and emotional goals may become more important. For example, for older ICD recipients, it is possible that, ‘*the willingness to suffer for a chance to postpone death may be felt more acutely by those nearer to death’* p1672 Finucane (1999) cited by Green et al. (2015). Older adults may adopt a more stoic view of their own mortality and accept the burdens of ICD device therapy in exchange for the security it may offer. They may also consider the risks of either worrying about or experiencing shock therapy, side effects, complications or ongoing device maintenance issues as being limited by virtue of their shorter remaining natural life. A ‘no need to know, no need to worry’ perspective appeared to prevail.

The apparent absence of ‘thinking slow’ systematic information gathering and processing of ‘system 2’ implies that a *Leap Of Faith* represents irrational or unsuitable decision-making. This is not necessarily the case. There is some suggestion that the change in emphasis from deliberative to emotional among older adults does not necessarily automatically lead to sub-optimal decision-making. An age related cognitive limitation may be associated with increasing selectivity in terms of attention to deliberative processing. This could promote a conscious, rational, deliberated choice to reach a decision based upon heuristics and satisfying emotional content (Peters et al., 2007). Shock, listen, accept and no need to worry, appeared to exemplify *Leap Of Faith* decision-making.

7.5.2 Aptitude For Health Literacy

Participants who adopted *Leap Of Faith* decision-making also had fewer years of formal education and displayed a lower aptitude for health literacy (HL) than the other patients studied, which may have influenced individual cognitive capacity and evoked heuristic processing. Fewer years in education and lower levels of educational attainment have previously been associated with lower HL (Chinn and McCarthy, 2013; Mäki et al., 2013; Gellad et al., 2011). A limited aptitude for health literacy (HL) constitutes an 'invisible barrier' to access to healthcare, involvement in patient-professional communication, healthcare decision-making and engagement with treatment modalities (Magnani et al., 2018; Wolfe et al., 2014). People with limited health literacy are less likely to ask fundamental questions or seek clarification of ambiguous information (Aboumatar et al., 2013; Katz, M. et al., 2007). It is associated with limited knowledge of healthcare conditions and treatment options. Vance et al. (2016) also concluded that being in employment could enhance cognitive reserve. Seventy five percent of the participants who used *Leap Of Faith* decision-making were retired compared with 33% in the other groups. Older adults who are more likely to be retired and have received less education may therefore be exponentially disadvantaged.

Limited understanding of complex healthcare information is not restricted to older adults or ICD technology. In England, 42% of working-age adults (aged 16-65 years) are unable to understand or make use of everyday health information, rising to 61% when numeracy skills are also required for comprehension (Roberts, 2015). Low HL, poorer understanding of health information and problems accessing or engaging with healthcare providers has been found to be particularly prevalent among people with cardiovascular disease (Magnani et al., 2018; Friis et al., 2016), heart failure (Cajita et al., 2016; Chen, A. et al., 2014; Matlock et al., 2010) and documented in ICD patients (Kim et al., 2013). Patients with an ICD for arrhythmic and / or cardiac disorders such as ischaemic cardiomyopathy were found to have decreased cognitive function at implant that deteriorated over the following 12 months (Kim et al., 2013). It is not clear whether it is the gravity assigned to having a heart problem or the complexity of these conditions that may affect cognitive ability. Nevertheless, the impact of advancing age upon functional HL is well documented (Eiser et al., 2018). A US assessment found that adult HL skills declined rapidly from the age of 55 years (Kutner et al., 2006). Adults >65 years are disproportionately affected by limited HL than their younger counterparts

(Kobayashi et al., 2014; Albert and Davia, 2011). US studies have found that almost 40% of 116 older adults over 65 years, recommended for CRMD have an inadequate or below basic level of HL (Hickey et al., 2015; Goldstein et al., 2014). Therefore, the complexity of ICD decision-making may perplex younger patients who maintain full cognition. This may be inflated in older age. An entrenched view of the traditional paternalistic model of healthcare may also affect the ability to communicate with HCP's and thus encourage a greater reliance upon expert advice (Wolfe et al., 2014).

E-technology and a reliance upon health related materials that exceed the reading ability of the average population may exacerbate the situation (Magnani et al., 2018). This is compounded by lower e-literacy (computer and internet literacy) skills, particularly among older adults compared with the general population (Watkins and Xie, 2014). This may disadvantage older adults further, particular in an era where e-technology is increasingly being used to communicate health information. Therefore, limited educational opportunities, socio and employment status and low aptitude for HL may have influenced individual cognitive capacity, affecting the ability to make sense of the information received and so discourage further enquiry and evoke a reliance upon heuristic processing.

Being younger, with more years in formal education, being in employment and a high score on the aptitude for HL scale was associated with systematic information processing and *Reinforced Acceptance*, *Reinforced Refusal* or *Reconsideration* decision-making. The characteristics of this group closely resemble patients with late melanoma who engaged in information gathering and were described by Garrett et al. (2019) as 'active insiders'.

7.5.3 The Impact Of High Or Low Monitoring

This is the first known study to explore the impact of self-assessed levels of monitoring upon decision-making among CRMD patients. Monitoring refers to the likelihood of engaging with systematic information gathering. High monitoring was found to be positively associated with increased desire and gathering of detailed health relevant information, especially in the face of ambiguous threat (Rood et al., 2015; Sie et al., 2013; Wakefield et al., 2007; Ong et al., 1999). There is a tendency to avoid such information and engage in distraction techniques among low monitors. The monitoring score was a significant contributor of the decision approach in this study. The association between *Leap Of Faith* decision-making, low mean monitor scores and a greater tendency towards heuristic information gathering was statistically significant.

In contrast, high monitor scores which corresponded with active systematic information gathering characterised *Reinforced Acceptance* and *Reconsideration* decision-making. Monitoring was also associated with more active involvement in cancer treatment decision-making (Rood et al., 2015; Timmermans et al., 2007; Wakefield et al., 2007; Ong et al., 1999). Notably, the highest monitor scores correlated with *Reinforced Refusal* decision-making. It is difficult to determine whether a categorical reason for this exists or whether one factor precedes another. Age, cognitive capacity, years in formal education, employment status, aptitude for HL and monitoring score could be independent, co-dependent or inextricably linked. Developing a valid and reliable assessment tool to determine the likelihood of systematic information gathering regardless of demographics, may inform the targeting of specific information giving. It is therefore feasible that a shortened version of the monitoring tool, comprising only of the CRMD scenario could provide a simple, efficient, user-friendly method of determining whether, or to what extent, monitoring coping styles might predict the likelihood of engaging with heuristic only or systematic information gathering.

This study has revealed that monitoring scores can predict the type decision-making. However, a number of interesting avenues are worth further exploration. Although an association between older age and lower monitoring was evident, several questions emerged that were not answered in this study. It was not clear whether monitoring was a product of nature or nurture. The literature suggests that low monitoring and reliance upon heuristic reasoning may be a function of advancing age and physiological cognitive decline. Therefore, if measured longitudinally, self-assessed monitoring scores would fall over time. On the other hand, some people may be naturally low on inquisitiveness regarding unfamiliar matters such as health, or they may choose not to monitor and make a conscious decision to avoid collecting information. Alternatively, it could be a consequence of fewer years in education and the educational approach of pre 1960’s. It is possible that education prepared individuals with fewer questioning skills, low level motivation to inquire and greater acceptance of authority, rules and protocols, therefore a lower aptitude for HL and monitoring. As such, younger people with more years in education may be exposed to contemporary educational strategies that foster curiosity, inquisitiveness and a more questioning mind. That is, younger people may have more opportunity to access and engage in further and higher education, which in turn may influence their approach to decision-making. Therefore, the relationship between age and decision-making may resolve over time. The answer to these questions could provide further clarity and evidence to support the development of targeted informational strategies.

The CRMD specific scenario potentially provides a predictive measure of the likelihood of sourcing further information. A focused study to test the validity and reliability of using only the CRMD scenario against the full TMSI, on a larger sample of patients would be required to support its implementation in practice. One area that was beyond the scope of this study was an appraisal of the potential impact of the controllability and predictability of the four scenarios upon self-reported coping styles. Coping is said to be influenced by the controllability and predictability of the situation (Miller, 1981). High controllability and predictability of an adverse event is associated with effective monitoring. However, monitoring is thought to be of little instrumental value in low controllability and predictability situations, when blunting becomes the favoured mode (van Zuuren et al., 1996). Therefore, an assessment of monitoring levels against the controllability and predictability of scenarios would be an interesting avenue for further study.

7.5.4 The Propensity To Worry

Emotions not only affect the initial thoughts surrounding a decision, or influence heuristic thinking, but are also thought to influence the depth of systematic information processing related to decision-making (Lerner et al., 2015; Cameron, 2003; Forgas, 1995). Matlock et al. (2017) observed evidence of emotion among ICD candidates but were unable to categorically determine the effect it may have had upon patient decision-making. In contrast, this study revealed that the intensity of shock, fear, panic and anxiety differed among the participants and appeared to influence both phases of decision-making. There is a dearth of research related to the potential influence of affective states, such as stress upon health decision-making (Ferrer and Mendes, 2018). Furthermore, much of the literature is concerned with the influence of affective states upon the adoption of health behaviours such as screening, help seeking, vaccination, risk reduction and lifestyle modification. However, its application to the process of decision-making for CRMD appears eminently feasible and deserving of further scrutiny. It became apparent that not only the initial shock response, but also inherent personality traits, such as the propensity to feel stress and anxiety appeared to influence the deliberative mode of decision-making.

An association between higher monitoring scores and higher trait anxiety has previously been reported, however the association between levels of monitoring and anxiety remains unclear in the literature (Wakefield et al., 2007; Miller et al., 2005). State and trait anxiety was not formally assessed using valid measures. However, during the Strand 2 interviews, participants openly verbalised their experience providing insight of their emotional state during the ongoing process of decision-making. For patients who employed *Leap Of Faith* decision-making, initial feelings of shock were generally moderated with a ‘matter of fact’, ‘for the best’ and / or ‘sense of relief’ attitude that a device might improve their life. These participants did not consider themselves to be prone to worry or anxiety, and described themselves as easy going, with an optimistic outlook, in matter of fact terms. This is consistent with Lucas (2012) and Agard et al. (2007), who also identified an association between a ‘matter of fact’ outlook and passive reliance upon the expert’s decision. This suggests an association may exist between lower trait anxiety and low monitoring scores.

In contrast, participants who adopted *Reinforced Acceptance* and *Reinforced Refusal* decision-making expressed feelings of ongoing stress and worry during decision-making. These findings would support an association between higher dispositional anxiety and higher monitoring scores. The desire to seek further information was in direct conflict with Janis and Mann (1977), who predicted that high level stress and anxiety would lead to non-adaptive coping strategies similar to *Leap Of Faith* decision-making. A recent study on the impact of stress and fear associated with cancer and information seeking or avoidance behaviour also found that high level stress accentuated a fear of cancer and was associated with information avoidance and limited knowledge (Vrinten et al., 2018). Whereas, no or minimal cancer fear resulted in information seeking and better knowledge. However, Vrinten et al. (2018) were concerned with information seeking behaviour among people who did not have a cancer diagnosis, which may account for the divergence in findings with this study. Furthermore, they used a researcher developed, single question Likert scale to assess perceived stress and cancer fear, which may have limited the value of the result.

In this study, it was difficult to know whether heightened stress and anxiety induced systematic information gathering or whether knowing more about device pros and cons enhanced levels of stress. Problem-focused strategies such as extensive information gathering and evaluation may be instigated to manage the objective threat. However, this may be adversely affected by anxiety or indeed induce heightened levels of stress (Folkman and Lazarus, 1985). That is, heightened anxiety may increase the likelihood of perceiving the CRMD to be further anxiety provoking, inducing greater emotional distress. Either way, systematic information processing was biased towards reinforcing the initial decision. When expert opinion, the view of significant others and previous experience were viewed in a positive light, further information gathering served to reinforce the decision to accept a device. Therefore, an element of confirmation bias also influenced *Reinforced Acceptance* decision-making. Thus, anxiety may have instigated 'direct' heuristic processing that generated the belief that CRMD would provide added protection, security and reduce the risk, as evident in their detailed description of the device, by all who accepted it. Furthermore, although this group received and understood verbal and written information regarding shock therapy, there was some evidence of avoidance of unpleasant imagery. Thus, when positive feelings were aroused or benefits perceived to be greater than the risks, CRMD technology symbolised security and protection against the increased risk of SCA.

When initial feelings of shock and fear were associated with an exaggerated sense of panic and horror, participants also engaged in systematic information gathering and *Reinforced Refusal* decision-making. That is, those who declined a device appeared to be the most anxious. When negative feelings are provoked, the risks maybe perceived to be too high and the benefits low (Finucane et al., 2000). Therefore, high level anxiety may perpetuate the potential for cognitive bias to occur. This may have incited the belief that CRMD is more risky and harmful. These participants described the device as an additional stressor and one that added unwanted additional complexity to their situation. Miller et al. (2005) had suggested a link between high monitoring, overestimation of perceived risk related to greater focus upon impending threats and therefore greater anxiety, though others did not identify a significant relationship (Wakefield et al., 2007). In this study, *Reinforced Refusal* appeared to prompt biases to interpret information in a way that minimised the threat and distanced the patients from it. For example, they readily placed greater faith in alternative measures including angiography, medication, lifestyle modification and purchase of a personal AED to enhance safety and therefore reject the need for CRMD. They did not however verbalise the potential benefits and harms associated with alternative options. In this study, actual and anticipatory anxiety appeared to attenuate the beneficial effects of device therapy enough to reduce engagement with it among those who declined. Thus, *Reinforced Refusal* may also represent an emotion-focused strategy adopted to reduce the level of distress. When the risks were thought to outweigh the benefits, CRMD appeared to signify an unacceptable stressor and a determined decision to decline a device ensued.

Cameron (2003) takes this one step further and postulates that increased anxiety leading to heuristic and systematic information processes may lead to the development of more extensive and detailed representations of illness and CRMD. This could affect the development of strong resistance to it. That is, patients may become adept at developing counter-arguments about the veracity of information gathered that questions or refutes beliefs (Cameron, 2003). This leads to counter-intuitive phenomena whereby the more an emotionally aroused individual attempts to gather information to generate evaluation, the greater the affective influence on the evaluation (Forgas, 2000). Anxiety influences information gathering which is assimilated against a backdrop of heuristics, such as memories and prior knowledge which may influence the evaluation of information gathered. Therefore, heuristics act as cognitive biases upon systematic information processing. Certainly those who demonstrated the type, *Reinforced Refusal* were able to recount their knowledge of device benefits and risks accurately. However, although not explicit in the interview transcripts, it is feasible that the innate aversion to device therapy did in fact suppress a willingness to consider device therapy in a positive light.

The participants who demonstrated *Reconsideration* decision-making initially displayed a more philosophical view. A matter of fact approach to the recommendation was associated with an equivocal, '*open to suggestion*' initial decision to accept or decline. *Reconsideration* also involved systematic information gathering and a more detailed and finely balanced review of the benefits and harms before a decision was made. However, this changed when they realised the potential risk of SCA and harm of device. Temporality considers shifts that might occur during decision-making. Therefore, changes in the perceived severity or frequency of symptoms, acquiring new information, new experiences such as an acute cardiac event, or changed circumstances such as rural living and increased distance from tertiary care centres may affect the ultimate decision. Inevitably, the initial wave of emotions and subsequent worry appeared to have a specific affect upon the immediate and ongoing decision. Focused exploration of the potential predictive nature of socio-demographic and situational characteristics for *Reconsideration* decision-making, maybe worthwhile.

In conclusion, the level of stress and anxiety experienced appeared to influence the degree to which participants engaged with active reinforcement. No or minimal stress was associated with minimal engagement and sole reliance upon expert advice to reinforce the decision. Some stress and anxiety inspired others to gather further information to reinforce the decision to accept a device. Whereas, a heightened state of anxiety stimulated some to collect information that reinforced their decision to decline. *Reconsideration* decision-making was associated with no or minimal stress, and effective engagement in information processing to balance the net benefits and harms, in order to reach a considered decision.

The potential impact of trait or dispositional anxiety upon decision-making has received far less attention and the interview schedule did not provide the opportunity to explore trait anxiety any further. Several well-known, valid and reliable measures of anxiety and depression exist. For the purpose of this study the addition of yet more validated scales to the Strand 1 survey was also rejected on the basis of the extra responder time and the onerous effort it would require. On reflection, assessing state and trait anxiety would have provided an interesting, informative and potentially more conclusive angle to this element of the discussion. The findings suggest some uncertainty regarding the impact of integral stress and dispositional anxiety upon the decision approach, the decision and potentially longer term outcomes. It was unclear, particularly with *Reinforced Acceptance* and *Reinforced Refusal* decision-making whether heightened anxiety influenced higher monitor scores and information gathering, or whether high monitoring and information gathering enhanced anxiety and thus affected the decision to accept or refuse a device. Further analysis of the potential impact of dispositional anxiety upon the deliberative phase of decision-making, acceptance and refusal is recommended.

7.6 Does The Type Of Decision-making Matter?

The type of decision-making governed the extent to which patients engaged in information processing, the degree of participation in decision-making and the level and accuracy of information recall and understanding. Only *Reconsideration* decision-making displayed a greater emphasis upon cognitive thinking, whereas although *Reinforced Acceptance* and *Reinforced Refusal* decision-making involved systematic information processing, they displayed an element of cognitive bias on a par with *Leap Of Faith* decision-making. While many cognitive biases in general decision-making have since been described, the study of heuristics in medical decision-making is limited and its role remains unclear. The extent of reliance upon heuristic and systematic information processing may not necessarily matter. Systematic processing may not be more desirable than automatic processes if knowledge acquisition is sufficient to make a decision (Lerner et al., 2015). However, differences in the extent to which patients acquired sufficient knowledge to give informed consent were apparent. Various factors such as the professionals approach, patient-professional interaction and perception of involvement associated with the decision-making type, appeared to affect knowledge attainment.

7.6.1 How Informed Were The Informed?

Previous studies have suggested that patients are generally not well informed when faced with healthcare decisions (Zikmund-Fisher et al., 2010a). The scoping review identified a general lack of understanding among ICD recipients (Chan et al., 2016; Groarke et al., 2012; Hauptman et al., 2013) but this was not associated with a particular sub-group or type of decision-making. A notable association found in this study provides a novel perspective. The main issue in this study was the significant difference in the apparent level of knowledge acquisition, recall and understanding among the participants. Furthermore, it was directly linked to the decision-making approach. *Leap Of Faith* decision-making was associated with limited recall, accuracy and evident misunderstanding of their underlying condition, the device role and function, and potential benefits and risks associated with living with it. Therefore, informed consent could not be assured. There was a general overemphasis upon known benefits with minimal recall of potential risks and harms. The level and accuracy of recall of information was lower than other participants. Green et al. (2015) also identified a notable deficiency in device knowledge and understanding specifically among older adults. Being well informed to consent to accept or refuse a device was associated with *Reinforced Acceptance, Reinforced Refusal* and *Reconsideration* decision-making. In contrast to previous studies discussed in the scoping review, a strength of this study was that data collection occurred within 3 to 6 months of device recommendation, and was therefore less likely to have been affected by memory lapse. The information seekers could reiterate what they had been told during consultations, and were conversant with the main device benefits and harms at the interview. This further corroborates the association between *Leap Of Faith* decision-making and low level knowledge. The association between inadequate knowledge and device refusal described by Chan et al. (2016) and Singh, N. et al. (2012) was not evident in this study.

When options and preferences are complex, ambiguous, unfamiliar and emotionally charged as in the case of CRMD, decisions may be more sensitive to the tone of voice, framing, word choice and the desired degree of collective participation (Epstein, R. and Street, 2011). This is important because information giving, couched in terms of benefit maybe highly influential.

7.6.2 A Positive Spin

Sole reliance upon expert opinion may account for the lack or misunderstanding of potential device harms. The ‘framing effect’ is a cognitive bias whereby individual choice may be influenced by the way information was presented, that is, as a gain, benefit or a loss, harm. There is a human tendency to avoid risk when a positive frame is presented, whereas a negative frame prompts risk seeking (Plous, 1993; Tversky and Kahneman, 1981). Thus, framing of information to focus predominantly upon the benefits of device therapy may lead to more risk averse decision-making by the patient, and an increased sole reliance upon the doctor’s opinion, so device acceptance to avoid the risk of SCA. However, this may discourage consideration of potential risks associated with the device. Conversely, greater emphasis upon the negative aspects could prompt risk taking, and accepting the risk of SCA as small and so decline. The influence of framing effects in healthcare decision-making has recently been disputed. Inconclusive results from a systematic review suggested that many variables appeared to influence the presence or absence of the framing effect (Gong et al., 2013). The study group acknowledged that an unexplained heterogeneity among the studies reviewed complicated comparison, but Gong et al. (2013) concluded that this did not preclude the possibility of a framing effect in some circumstances. An association between benefit bias and acceptance was notable in this study. This not only involved *Leap Of Faith* decision-making, but also the active information seekers who accepted the device despite them being more critical in their judgement. The participants also referred to the persuasive effect of the strength of tone and language used to emphasise the benefits of CRMD by physicians. This is consistent with findings from the scoping review (Hauptman et al., 2013; Matlock et al., 2011; Agard et al., 2007).

In general, the participants in this study were better informed about the possible, immediate peri and post procedural physical complications of device implantation compared with Hauptman et al. (2013) and Groarke et al. (2012). However, some omissions became evident in this study, including the relatively common but distressing complication of diaphragm pacing. Mid and longer term issues such as deactivation, battery change, potential device replacement and inappropriate shocks were not routinely included. This was consistent with other studies (Stromberg et al., 2014; Herman et al., 2013; Hauptman et al., 2013; Groarke et al., 2012). Matlock et al. (2017) observed evidence of framing effects throughout interviews with 48 patients who had been recommended for a primary prevention ICD. They also found that survival benefits were overemphasised, whereas discussion related to battery changes, receiving shocks and deactivation was limited or excluded. This may explain why overestimating the benefit and underestimating the risk of ICD is often reported by patients (Sandhu et al., 2019; Green et al., 2015; Stewart et al., 2010). In this study, most participants had the opportunity to discuss social issues such as driving, flying, sports and sexual activity. However, as previously reported by Hauptman et al. (2013) emotional concerns were less frequently considered with twenty eight (56%) denying any conversation.

Matlock et al. (2017) also described a strong default effect in favour of device implantation. This was based upon the ICD patient's perception of the view of the clinician. That is when the patient felt that the clinician believed it was the right thing to do. This was clearly evident in this study, as there was no suggestion that the clinicians were either impartial or contrary to device implantation among those who accepted a device. Truly rational choices should be based upon '*perfect information, a perfect grasp of their objectives and the perfect ability to use the information to make decisions to further their objectives*' p.3 (Vlaev, 2018). This would require clarity upon the potential risks of SCA, benefits and harms of primary prevention device therapy. This in itself, is largely unknown to the expert and at the mercy of speculation (NICE, 2014). Therefore, a rigid reliance upon statistical data represents the fallibility of information giving. Ultimately, the degree of uncertainty attached to a particular decision is inextricably linked to the unpredictable and therefore unknowable nature of potential device benefits and harms for a particular individual. Therefore, providing a risk profile for SCA for different disorders, especially inherited conditions is particularly challenging. Online SCA risk assessment tools for inherited disorders are available and were introduced to some participants with HCM / ARVC by the consultant or ICD nurse. Others were given an approximation of risk, otherwise risk profiles were not discussed. However, when asked whether they found it useful and if not, whether they would have appreciated it, there was a general lack of desire for, and belief that statistical information related to personal risk of SCA, device complications and shock therapy would have helped their decision-making. Patients need a definition of 'need' that they can apply to their circumstances.

Importantly, assessing patient values, beliefs and preferences for a treatment is acknowledged as best practice. Yet, cardiologists have admitted that mortality data and adherence to practice guidelines took precedence over patient preferences in their recommendation (Caverly et al., 2012). The HCP emphasis upon device capabilities, preventing SCA and the potential to improve symptoms through re-synchronisation, based upon current evidence and guidance is neither inappropriate nor misguided. Nevertheless, being well-informed and incorporation of patient values, goals and preferences are a measure of effective decision-making. In this study, few patients recalled being asked for an opinion, and when they were some had struggled to articulate their wishes. However, although eliciting and incorporating patient preferences in to decision-making is advocated, Carroll et al. (2018) concluded that patients contemplating ICD implantation experienced difficulty in interpreting and articulating their values and goals. They recommend reframing reference to values in terms such as '*what matters to you'* and '*what is most important'* p1953 (Carroll et al., 2018).

In summary, the findings do not mean that insufficient, irrelevant or misinformation was conveyed prior to ICD implantation. However, a more balanced view of device benefit and harms may enable a more balanced decision to be made, if the current gold standard in informed consent and supporting patient choices about health and care is to be achieved (NHS., 2019; GMC., 2018). Particularly as the proportion of individuals living in the >80 years group increases, so does the subsequent demand for healthcare. In addition, the move away from paternalism and increasing emphasis upon self-determinacy means that patients should be encouraged to engage in decision-making. This creates increasing challenges for decision-making. The level of recall of information associated with *Leap Of Faith* decision-making was limited. This may represent a choice preference for these participants, however the level of informed consent was questionable. Furthermore, reliance upon other sources to reinforce decision-making may not lead to truly informed, autonomous choice as patients may have limited insight in to their own cognitive biases and limitations. Therefore, in reality, informed consent may be an unattainable ideal or a quest for the best. It has been described as 'bureaucratic legalism' (Gainer et al., 2017). Alternatively, perhaps it should be acknowledged that a perfect, rational, fully informed decision for or against CRMD cannot be made. A more realistic view would be that individuals engage with 'nudged choice' based upon what is known at the time rather than 'informed choice'. The concept of 'nudging' people to make better decisions in a more sophisticated manner than mere provision of information has been making ground in recent literature (Vlaev, 2018; Thaler and Sunstein, 2009). A re-emphasis upon patient choice rather than informed consent might be appropriate.

7.6.3 Feeling And Being Involved And Well Informed

Without exception, the participants in this study believed that they had been actively involved, well informed and instrumental in making the decision during the given time to deliberate. Previous typologies of decision-making focused upon the level of collective participation from uninformed passivity, to shared decision-making and informed autonomy (Flynn et al., 2006; Charles et al., 1999). Flynn et al. (2006) polarised participants in terms of relinquishing or retaining control for the final decision, with or without deliberation. There are some commonalties with the typology of decision-making emerging from this thesis in terms of the level of deliberation. However, the level of collective participation described by Flynn et al. (2006) and Charles et al. (1999), is not directly reflected in this model.

Studies have identified patients who value the expert's advice and relinquish control for the decision to the expert, as passive decision-makers (Garrett et al., 2019; Carroll et al., 2018; Flynn et al., 2006). Although *Leap Of Faith* decision-making displayed no desire for further information gathering, the participants in this study did not experience complete passive decision-making. Participants were given the opportunity to state their decision even though in each case it was wholly based upon expert opinion. Therefore, rather than perceiving their role to be limited, the participants who relied upon expert opinion in this study believed that they had been involved in or in fact retained control of the decision. Expert opinion served to reinforce their decision to accept. Having the ultimate say in the decision based upon the expert's recommendation was construed to be adequate involvement. This resonates with previous findings by Smith, S. et al. (2009). They described a relationship between educational background and the construed level of involvement in decision-making (Smith, S. et al., 2009). For patients with lower education, involvement revolved around consenting to a recommended option and adopting responsibility for the ultimate decision by agreeing with the option recommended by the physician. The older participants who adopted the *Leap Of Faith* approach, considered themselves to have been sufficiently well informed in reaching the ultimate decision. Therefore, they may make a very sound rational decision in choosing to believe information that is accessible and sounds applicable to them, and accepting the recommendation provided by the expert.

Alternatively, deliberative autonomists were said to actively, take control of the decision based upon further information seeking (Flynn et al., 2006). There were similarities between *Reinforced Acceptance* decision-making and deliberative autonomists. The acknowledgement that HCP's are not infallible prompting the need to verify what the HCP had told them resonated in this study. Participants who *Reinforced Acceptance* perceived their role outside the consultation to be equally important, and independently sought further information from written, web based and / or second opinion sources to reinforce acceptance of the expert’s opinion. The participants in this study were well informed, however the level of autonomy exhibited was unclear. They firmly believed that the final decision was very much driven by expert opinion and had not considered alternative options or considered life without a device. *Reconsideration* and *Reinforced Refusal* decision-making exhibited some autonomous choice however the former type referred back to expert opinion once the perception of clinical need became evident. Those who declined the device also sought information to reinforce an independent decision to decline. The findings support a consistent trend away from a medically driven, passive process towards active, collaborative participation.

The type of collective participation may not be as relevant as the impact upon decisional outcomes. The cancer literature suggested that patient perception of involvement and control rather than actual level of involvement and control, may be sufficient to promote decisional satisfaction, less anxiety, depression and decisional regret. Therefore, this thesis focused upon the patient’s perception of desired and actual participation and the degree of match achieved as a marker of decisional satisfaction. Thirty one (62%) participants in this study reported a complete match and 38% a degree of mismatch. This was in agreement with a meta-analysis of studies that had used the Decisional Control Preferences Scale and reported that 61% of patents had achieved their preferred role (Singh, J. et al., 2010). A longitudinal study to determine the extent to which a match between desired and actual participation affects longer term outcomes is warranted.

Smith, S. et al. (2009) found that participants with higher education and HL described their level of involvement with decision-making as participatory or shared with the HCP. In this study, 4 participants had desired a collaborative approach but only 2 reported joint decision making. Stacey et al. (2017) and colleagues have long advocated shared decision-making (SDM) strategies as a vehicle for supporting informed decision-making. SDM alleges to promote involvement of patient preferences in decision-making and result in better health outcomes, experiences and costs (Lewis et al., 2018; Stacey et al., 2017). SDM thought to formalise this process, can only truly occur if patients are fully prepared with relevant information to match that of the clinician. Pre-requisites for SDM include unbiased clinical evidence, clinician communication expertise and patient awareness of personal preference and goals (Sandhu et al., 2019). In reality, this rarely occurs. Participants in this study valued the support and being accompanied by spouse, family or friends not least as an additional memory to help assimilate and retain information. This resonates with previous studies (Carroll et al., 2018; Fisher et al., 2018; Gainer et al., 2017). Rather than SDM, collaboration where patients receive fundamental medical and device related information and clinicians receive insight in to the patient’s preferences, values and goals may be more appropriate (Eiser et al., 2018; Politi and Street, 2011). Though some participants stated that they preferred and experienced collaborative decision-making, the extent to which this occurred was unclear and warrants further investigation.

Half the participants who demonstrated *Leap Of Faith* decision-making reported seeing the consultant and then being abandoned to make sense of the recommendation and reach a decision. Therefore, information exchange was limited by the length of physician’s consultation time and may account for the lower level recall associated with this type of decision-making. For the others, the ICD nurse served to reinforce the consultant’s advice, and provide more detailed discussion regarding device benefits and harms to support the decision they had made. The extended time available to the ICD nurses consultation, and the opportunity to repeat information appeared to enhance recall of information. However, an ICD or HF nurse was not available on all clinical sites. Some patients were seen by the consultant and then a pre-implant assessment nurse, by which time the decision had already been made. The role of the ICD and HF specialist nurses were instrumental in affecting information recall. However, some patients were denied the opportunity due to pressures on the service or a lack of specified role. Several participants in this study expressed the view that a multi-participatory approach involving physicians and specialist nurses (though not necessarily at the same time), and the patient and significant others would be appreciated. An emphasis upon involvement of an ICD specialist nurse to complement the shorter consultation time available to the physician is highly recommended.

Decision aids may provide an alternative mechanism to support information exchange. They are said to enhance knowledge acquisition of benefits and risks, involvement of patient preferences and greater patient participation in the decision-making process (Stacey et al., 2014). Furthermore, they reputedly benefit disadvantaged patients with lower HL more than those with higher HL and socio-economic status (Stacey et al., 2017). Despite this, decision aids were not evident in local practice. Recent studies to evaluate the efficacy of a range of patient decision aids (PtDA’s) have reported mixed results and noted some challenges with implementation (Eiser et al., 2018; Carroll et al., 2014). Furthermore, health care professionals report being either ill-prepared or unconvinced of a place for SDM and decision aids.

7.7 Decisional Doubt And Regret

Empowering patients to exercise their autonomous right to informed consent, achieving decisional satisfaction and avoidance of cognitive dissonance, conflict and regret are evidence of effective patient decision-making. Contradictory evidence of a relationship between monitoring scores, level of engagement and information recall, and decisional conflict or regret exists (Orom et al., 2016; Sie et al., 2013; Timmermans et al., 2007). Therefore, the pre-validated Decisional Regret Scale (DRS) (Brehaut et al., 2003) previously used by Hickman et al (2012 and 2010) was adopted in this study to assess whether participants experienced decisional regret, and whether this was associated with monitoring scores. This survey revealed minimal levels of decisional regret across the participants which was corroborated during the interviews. Furthermore, there was not a statistically significant difference between the type of decision-making, or acceptance versus refusal and regret. This corroborated findings from the scoping review studies (Groarke et al., 2012; Singh, N. et al., 2012; Hickman, 2010; Agard et al., 2007). Hickman (2010) did conclude that informational monitoring coping styles may predict decision regret, however the evidence for this remains unclear. A correlation between monitoring scores and decisional regret was not evident in this study.

In summary, the four types of decision-making revealed in this study, provides a unique insight into the way participants contemplating primary CRMD implantation approach the decision. Decision-making occurred in two distinct phases. An immediate impulsive decision to accept a device was based upon positive heuristic thinking, the perceived strength of recommendation, marked symptoms and clinical need, and a desire to prolong life and prevent SCD. Device refusal was associated with negative heuristic thinking, minimal symptoms and low perceived need, and a preference for quality over quantity of life. This was followed by a period of deliberation. *Leap Of Faith* decision-making describes an uncritical reliance and acceptance of the expert's opinion to inform the decision. *Reinforced Acceptance, Reinforced Refusal* and *Reconsideration* decision-making was associated with independent information gathering and processing to evaluate the pros and cons of device therapy. Information gathering that served to reinforce the expert's opinion was manifest in *Reinforced Acceptance* decision-making. In contrast, *Reinforced Refusal* decision-making was associated with information gathering to strengthen the resolve to refuse device therapy. *Reconsideration* decision-making represents some hesitation and a change of mind based upon an evaluation of the pros and cons of device therapy.

The theoretical model of patient decision-making for CRMD illustrates the range of socio-demographic and situational factors that appeared to influence the decision approach and device acceptance and refusal. *Leap Of Faith* decision-making was associated with older age, IHD, a lower aptitude for HL, less educational years, low monitoring scores, and a relaxed, matter of fact outlook. Middle age, a higher aptitude for HL, more educational years and high monitoring characterised *Reinforced Acceptance* and *Reconsideration* decision-making. The propensity to worry about the decision distinguished *Reinforced Acceptance* from *Reconsideration* decision-making. *Reinforced Refusal* decision-making was associated with being younger, a higher aptitude for HL, more educational years, having the highest monitoring and a heightened levels of stress and anxiety. The level and accuracy of knowledge acquisition, information recall and informed consent characterised the alternate decision-making journeys. *Leap Of Faith* decision-making was associated with limited knowledge and understanding compared with the other types of decision-making. It is feasible that the influencing factors could be used to predict the type of decision-making a patient may adopt and so inform a targeted system of information exchange.

7.8 The Strengths And Limitations Of This MMR Study

Every effort was made to ensure that robust measures were put in place to promote study validity, reliability, transparency, trustworthiness and rigor. The rationale for, and challenges with selecting a mixed methods approach are discussed in detail in Chapter 3. Chapters 4, 5 and 6 present a detailed analysis of the research methods employed for Strands 1, 2 and 3 respectively, with reference to issues of validity, credibility, integrity and transferability. Frequent and detailed discussion with academic supervisors, Dr P Marshall and Dr J Maclean, focused upon process, progress, practice and challenges throughout the project. The following sections will address issues not covered in detail in previous chapters.

7.8.1 The Study Strengths

A multi-disciplinary approach to CRMD implantation is now common practice in cardiology. However, there are differences in the service provided leading to slight variation in the pre-implant recommendation and preparation ‘events’. Therefore, a multi-centre approach was adopted to account for the potential effect that different service experiences may have upon decision-making. It was also hoped that this would enhance recruitment efficiency, though this was not the case.

The development of a conceptual map, based upon the general decision-making literature and scoping review, provided a clear sense of the elements that required further investigation. This enabled the development of clear and focused objectives to provide detail and direction for the research aims. This is the first study known to have included a self-assessment of monitoring scores leading to an analysis of the potential impact upon patient decision-making. The research methods selected for this study sought to replicate previous similar studies where possible. This included the use of various pre-validated data collection instruments to enhance the validity and reliability of data collected. For example, the quantitative Strand 1 survey included the Threatening Medical Situations Inventory (van Zuuren et al., 1996) to enable self-assessment of monitoring scores. The questionnaire included a bespoke scenario concerned with CRMD to enhance the relevance to the participants. The Decisional Control Preferences Scale (Degner et al., 1997b) and Decisional Regret Scale (Brehaut et al., 2003) were also used for data collection. A small group of service users were involved in the development and construction of the questionnaire. They verified the relevance and precision of the survey. The survey was tested for clarity, comprehensibility and timing by a larger group of CRMD recipients. The only amendment required was the predicted time required to complete. The questionnaire was made available on paper, which suited the majority of participants, and via email and online. Unlike previous retrospective studies, data collection usually occurred within 3, and no more than 6 months of the decision. This therefore reduced the potential for problems of recall associated with retrospective study and may enhance the reliability of the findings.

A particular strength of this study is the examination of cognitive bias in a real world context. Previous studies on the impact of cognitive bias upon decision-making had revolved around hypothetical scenarios. The qualitative Strand 2 of this study focused specifically upon thoughts, feelings and actions at the time of the decision. Service users were also involved in constructing and checking the interview questions. In order to maintain consistency and comparability the interviewer conformed closely to the schedule. This prevented too much digression on to other aspects of the implant experience, yet allowed the participants sufficient freedom to elaborate on the questions and prompts. Inevitably, the first few interviews allowed some slight variation in subsequent interviews to accommodate details emerging from the previous participants. Issues of credibility and transparency were addressed through regular supervisory meetings which involved detailed discussion at every stage of the thesis development. Appraisal of the survey findings and application of various statistical analysis methods were discussed and agreed. The Strand 2 element of the thesis inevitably generated a large amount of narrative data. Coding interview data was complex and resulted in several versions of the code book. However, cross checking by two academic supervisors verified the process. The only differences were that AMK had included more detailed coding compared with PM and JM who remained faithful to the narrative related to research questions only. Thematic analysis adopted an iterative process led primarily through regular, rigorous, explicit and detailed academic discussion. As sub themes and themes emerged, discussion regarding their organisation and meaning ensued. This formed the basis for the framework analysis and data integration. The framework and joint displays were deliberately populated with detailed data to allow readers to follow researcher reasoning and interpretation. Qualitative analysis is by its very nature at the mercy of interpreter bias. Therefore, in order to enhance authenticity, a summary of the findings and theoretical model were presented to a small group of patients.

A major strength of this thesis was the data merging and integration of Strand 1 and 2 data into Strand 3. MMR is frequently criticised for failing to address this aspect of the methodology. Initially, as data collection and analysis for Strand 1 and 2 ensued, it was anticipated that Strand 3 would fail to reveal anything new. However, this was not the case. For example, the impact of symptomatology and issues regarding patient perception and reporting of symptom severity only became evident during merging on to the joint display. In addition, some discrepancies between answers given on the questionnaire and at the interview stage came to light during merging. This was not merely accounted for by the way the questionnaire was developed or presented. For instance, some participants stated on the survey that they had not seen an ICD specialist nurse prior to implant, yet discussed this at interview and vice versa. Furthermore, participants indicated what they recalled being told during the consultation on the survey, yet they could not always reiterate it at interview. This allowed an assessment of the extent of recall and understanding of that information. Finally, despite reporting a preference for active control on the survey, it became evident during interviews, that *Leap Of Faith* decision-making was associated with a tendency towards passive decision-making. The opportunity for extended scrutiny of the data through merging also enabled an assessment of the accuracy of data collection methods. It was evident that the survey had failed to capture some nuanced findings which became apparent during the interviews. Although this could be perceived to be a limitation, it also presents a strength because comparing and contrasting findings from each strand was used to confirm and refute initial findings, resulting in robust results in Strand 3.

7.8.2 Areas Of Weaknesses Emerging From The Study

Inevitably with any research project, particularly at the hands of a trainee researcher, some areas of weakness were exposed for consideration. Exposure and explanation of the limitations is in itself a strength in terms of transparency, transferability and trustworthiness. It was acknowledged that selecting a sequential rather than a concurrent MM design, to allow Strand 2 interviews to develop from the Strand 1 surveys, would have facilitated more robust mixing at the data collection stage. Study time constraints and issues of memory recall, if interviews were conducted much later, precluded this. However, surveys were referred to during interviews and any missing data was collected at that time, improving the overall response rate.

The decision not to use validated instruments to assess participant health literacy and dispositional anxiety was unfortunate. The focus upon self-assessed monitoring was a priority for this study because it had not featured in similar studies with ICD patients before. The findings from the literature and scoping review also suggested that further focus upon decisional outcomes such as control preferences and regret was warranted. Therefore, extending the length of the questionnaire with inclusion of HL and anxiety assessment tools was considered to be too excessive in terms of participant time and effort, and could have had a negative effect upon response rates.

The interview question development posed some challenges. Firstly, the degree of planned structure created a dilemma. The order of questions assumed a particular patient journey. Though this allowed some degree of focus and provided the interviewer with the reassurance of an aide memoire, it may have been construed as rigid and leading. However, as a novice interviewer the fear of collecting abstruse data arising from an entirely open question was equally problematic. Therefore, a combination of semi-structured questions with intermittent open ended prompts were included to allow individuals to elaborate upon their own experience. Secondly, reliance upon the pre-defined concepts to inform questions may have missed some crucial aspects of the process and there was some apprehension related to the dependability of questions to reflect the desired information. Nevertheless, for parity the same guide was referred to throughout data collection, despite the potential restrictions this may have imposed. Interviewees did elaborate upon some issues however, this either detracted from the focus upon decision making, represented repetition or it failed to present new avenues worthy of exploration. Therefore, there was no need to refine the schedule during data collection or analysis. Some questions came to light post data collection during the analysis stage. For example, participants were not asked what if anything might have changed their mind for fear of promoting unrecognised uncertainty, regret or influencing a decision to decline. Yet some interview transcripts, particularly from those who had declined a device, clearly provided some answers for this, such as an equivocal VT diagnosis or '*hard factual data'*. Similarly, it became apparent that the questionnaire did not ask whether there had been a time when they had considered not accepting a device. This may represent some important missing data related to uncertainty and doubt.

Survey and interview questions are based upon the assumption that respondents can readily retrieve representations of what was known, preferred, valued and believed at the time of the decision. In reality, answers to such questions may well represent what was known at the time of data collection, which may or may not have been available at the time of the decision. Therefore, responses could and at times did, represent learning post implant for some participants. Efforts to minimise this included data collection within approximately 12 weeks of the implant, though this still could not guarantee that responses reflected the pre-decision rather than post-decisional experience.

As a result of the smaller than planned sample size for Strand 1, the findings must be considered with some caution. A failure to reject the null hypothesis could indicate a real lack of relationship between variables. Alternatively, it could represent a type II error, that is an inability to detect a difference due to small sample size (Gray, J. et al., 2017). This was carefully considered throughout analysis and interpretation of the Strand 1 data.

Limitations of the framework approach revolved around the organisation of the data. Charting narrative data in a spreadsheet format may tempt quantification rather than qualitative analysis, and initially it did. Initial quantification of coding was time consuming, resource intensive and superfluous to need and was therefore abandoned. A further limitation of remaining rigidly to the original codes developed specifically to answer the research question risked overlooking important data. Conversely, searching for evidence of emerging codes from one transcript across the others could represent analytical bias, such that codes are made to fit themes. Verification of coding, indexing and charting at regular supervisory meetings ensured that this was not the case.

7.8.3 Reflection And Reflexivity

The distinction and similarities between reflection and reflexivity have been described in the literature (Dowling, 2006). Reflection refers to learning through an in-depth examination of an event external to oneself. Whereas, reflexivity is akin to self-awareness, self-appraisal or self-critique of the relationship between the researcher and the researched (Lamb and Huttlinger, 1989). It is concerned with analysis of the influence of ones attitudes and beliefs, thought processes, assumptions and experiences upon each stage of the research project (Koch and Harrington, 1998). The role of reflection on reflexivity is central to qualitative research yet the separation of nurse from researcher is acknowledged as problematic (Dowling, 2006). Ideally collection and analysis of each data set should be completed independently by different investigators, blinded to the other data to minimise potential bias. To enable researcher training this was not appropriate, therefore the PI completed both aspects. Maintaining a reflexive diary enhanced awareness and consideration of the potential impact of the researcher upon the researched. Examples from a reflexive dairy are described below.

The dual role of nurse and researcher may be the factor that promotes patients to participate in a research study. To mitigate against this, clinicians acted as gatekeepers and facilitated the first contact with potential participants. The PIS and Strand 1 study pack was then posted or emailed to participants once they had invited contact. Furthermore, the opportunity to participate in Strand 2 interviews was offered at the end of the survey, therefore involvement or not, in one or both strands of the study was at the prerogative of the participants. Nevertheless, the potential for an element of Hawthorne effect could not be avoided as participants were aware of the researcher’s background in cardiology. This was considered a strength in terms of understanding the enormity of the participant’s experience. However, it may have compelled participants to present their experience in a positive light. Furthermore, there were instances when participants asked questions pertaining to their device. Inevitably, the role of the nurse became explicit and answers were given. These events were documented and coded as examples of a lack of knowledge and recall.

The initial aim of the study was to include BME groups, however, the study failed to recruit any non-white participants. Naively, it was assumed that participants from varied religious and cultural backgrounds would be interested in participation. Therefore, this angle of inquiry lacked sufficient careful planning. Access to local communities outside the acute Trust environment, by people of similar faith and ethnicity may have enhanced recruitment. Involvement of patients and public from minority groups, in the planning and execution of a similar study to explore BME patient decision-making, may promote greater recruitment success. It also became clear during the empirical investigation that valid measures of health literacy and state and trait anxiety, may have been more interesting, enlightening and worthwhile in establishing factors that influence decision-making, than the focus upon decisional control preferences and decisional regret.

As a reliance upon the expert opinion heuristic (Dr, nurse, physiologist) as a powerful and quite possibly the optimal source of information emerged, the possibility that researcher preconceived ideas about participant levels of knowledge and recall could influence the findings. To combat this, care was taken to ensure that the same questions related to their knowledge were carefully posed and repeated in the same way at every interview. During early interview transcription, the opportunity to really listen to the participant exposed the realisation that the interviewer was intent upon on asking all the questions, rather than listening and responding fully to the participant. For example, during the second interview, the participant appeared to be quite superficial and monosyllabic. It was not until transcription and repeated listening that the richness, depth and power of the participant's words and meanings became more evident. This induced a greater awareness of the subsequent interview technique and focus upon listening skills.

One participant who declined an ICD did eventually accept a CRT-P once they were aware that the devices could be implanted independently. The participants resolve to decline and reticence to reconsider, unlike the other two participants was particularly notable and may have deserved a unique identifier. However, as a result of researcher naivety at the point of interview, the opportunity for further questioning around whether a CRT-D would have been accepted had a CRT-P not been available was missed. That said, further questioning may have stifled the participants willingness to openly talk. Another interview involving a participant from the healthcare field, tended to be more of a 'chat' than an interview. There was a sense that questions, prompts and responses may not have been yielding the required information. A conscious effort was made, to remain vaguely attached to the interview schedule without making the interview too closed, while maintaining as open a discussion as possible. The interview revealed some rich data about the entire personal experience of the condition, decision-making and the lead up to the implant. However, it was not always specific to the actual process of decision-making. This presented a dilemma in terms of the time devoted to the interview and degree to which the data could be used. Furthermore, some issues were interesting but pursuing them in other interviews, risked an element of digression from the research question and aims. Finally, potential assumptions regarding the participant's level of and desire for knowledge, may have influenced the researcher focus away from identifying potential heuristic thinking. This was problematic however, the process of reflexivity ensured that future interviews were consistently re-directed to concentrate upon decision-making.

Although the participants had already made their decision, a recurring area of discomfort was raising issues such as, the risk of complications like infection, lead displacement and discussing shock therapy. As some participants had not dwelled upon this prior to device implantation, concerns regarding the potential to sow seeds of doubt, regret or anticipatory anxiety became a challenge. It became evident that some participants had avoided information and played down the issue of device implantation. There was an element of researcher prior expectation that all participants might display significant levels of concern or anxiety as a result of the seriousness of the cardiac condition. While this was so, reflexivity ensured that such preconceptions did not obscure the exploration of the patient perspective. The varied accounts of the predisposition to worry or not among the participants provided reassuring evidence of this. Finally, during the analysis, merging and interpretation stages, there were times when being so entrenched in the data, it was difficult to see the 'wood for the trees'. Therefore, bouncing ideas with colleagues, peer PhD students and in particular academic supervisors helped to develop the clarity and vision required to tease out the threads and issues and so begin to see the 'wood'.

7.9 Key Messages And Implications For Practice

Whether recipients decide to accept or refuse a device is of little consequence when the decision is clearly informed. Whether a healthcare decision appears somewhat irrational or in opposition to the expert view, it is inappropriate to question or feel uncomfortable with the judgement of a well-informed person. Most of the participants in this study knew what they had signed up for. However, it was evident in this study that some recipients were not well informed to consent. Table 7.1 presents 5 key messages arising from this thesis.

Table 7.1 Key Messages Arising From This Thesis

1	This study has strengthened the debate regarding the influence of heuristic thinking upon patient decision-making
2	Four types of decision-making, *Leap Of Faith, Reinforced Acceptance, Reinforced Refusal* or *Reconsideration* are prompted in response to a recommendation for primary prevention CRMD
3	A range of socio-demographic and situational characteristics appear to predict and influence the type of decision-making and acceptance or refusal of a device
4	Low monitoring was associated with information avoidance and high monitoring with information seeking behaviour among this group of participants
5	The level of knowledge acquisition and recall was variable and did not always assure informed consent

Further to this, table 7.2 presents a number of potential implications for current practice.

Table 7.2 Implications For Practice Arising From This Thesis

1	Monitoring scores could provide a practical assessment of the likelihood of engagement with systematic information gathering, in order to tailor information giving strategies appropriately
2	A more balanced view of device benefit and harms may enable a more balanced decision to be made in order to achieve the current gold standard in informed consent and supporting patient choices about health and care
3	A more realistic view maybe that individuals engage with ‘nudged choice’ based upon what is known at the time rather than ‘informed choice’. A re-emphasis upon patient choice rather than informed consent may be appropriate
4	A greater focus upon the participant’s emotional disposition and concerns is needed
5	An emphasis upon involvement of an ICD specialist nurse for all patients, to complement the shorter consultation time available to the physician is highly recommended
6	A targeted support framework could tailor information to meet the needs of different types of decision-making. For example, i. Information displayed as a ‘RAG’ colour coded memory aid to represent anticipated outcomes may better support age related decline in the efficiency of deliberative information processing. ii. Conversing with ICD recipients through monitored internet chat rooms and smart phone avatar apps, using 3 minute clips to assess knowledge of cardiac condition, describe role and function, benefits and potential harms, and personal goals may appeal to younger audiences
7	Clinical psychologists may be best placed to provide additional specialist support to those with an exaggerated fear of their own mortality, the burden of technology and the stress of decision-making

7.10 Recommendations For Future Research

On reflection, researcher learning achieved through undertaking a PhD study, was perhaps gleaned as much from what should have been done as what was done. Moreover, this study has perhaps revealed more questions than answers. A wealth of interesting angles open for further investigation have been revealed within this chapter and some are summarised in table 7.3 below.

Table 7.3 Recommendations For Future Research	
1	To test the utility and validity of the theoretical model of patient decision-making for CRMD on a larger sample of patients
2	To explore the decision-making experience of women and BME groups contemplating primary CRMD to inform the development of tailored mechanisms to support these specific groups
3	To examine the impact of symptom severity upon decision-making and the usefulness of the NYHA scale as an assessment tool is required
4	To test the usefulness, validity and reliability of using the CRMD scenario monitoring assessment tool, to determine the likelihood of systematic information gathering on a larger sample of patients
5	An assessment of dispositional anxiety using a valid tool such as the short form STAI (Marteau and Bekker, 1992) to examine the association or propensity for heuristic only or systematic information gathering
6	An observational study to assess the level of collaborative participation in decision-making during consultation events, and determine the usefulness of tailored informational strategies
7	A longitudinal study to determine the extent to which increasing information overwhelms, burdens or enlightens decision-makers and the effect upon decisional satisfaction, regret and coping with and without CRMD

7.11 Conclusion

The motivation to undertake this study emanates from a long standing interest in the general welfare of patients with complex cardiac devices, and the evident lack of UK specific research related to the patient’s decision-making, revealed in the scoping review. The scoping review was published in a peer reviewed journal (Malecki-Ketchell et al., 2017). The study aimed to explore what influences patient decision-making in accepting or declining primary prevention CRMD. In undertaking this study, a balance between breadth of generalisation and depth of understanding and meaning, within the time and resource constraints of a PhD project were considered to be essential. A mixed methods approach was therefore chosen to provide a comprehensive understanding of factors which influence patient treatment decision-making. Ensuring rigor, data quality, validity, credibility, transferability and confirmability was paramount throughout this thesis. Therefore, the chapters present a detailed analysis and rationale for every aspect of the study. Service user-carer participation, supervisor validation, thick description and reflexivity were adopted to promote authenticity.

This study has revealed a new typology of decision-making making that provides a unique contribution to the current state of academic knowledge and interest in this field. It has established a range of factors that appear to influence and may predict the type of decision-making adopted in response to a recommendation for primary CRMD. Greater insight and appreciation of the way in which the patient arrives at a decision to proceed or not with implantation, and their preferred informational coping style, provides the evidence to support a framework of tailored information and communication practices to enable effective, collaborative decision making, to meet the demands and requirements of specific needs and situations, to facilitate truly informed choices, and help acceptance and adjustment to life with technology. The implications for practice are considered and a range of recommendations for post-doctoral study are proposed. Findings from the research will be disseminated through scientific publications in peer reviewed journals and conference presentation pertinent to healthcare professionals in the cardiac field. Undertaking this research has satisfied an intellectual curiosity, developed researcher skills and contributed new and important scholarly knowledge to the field.

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APPENDICES

Appendix A Normative Decision-making Theories

Normative (Classic) Decision-making Theories		
Theory	Author & Date	Key Features
Expected Utility Theory (EUT)	Von Neumann and Morgenstern (1944); Bernoulli (1954)	Rational decision maker utilises probability of benefits and consequences from all possible options to choose option with highest, optimal expected utility or value. Decision analysis assumes efficacious therapeutic decisions be based upon maximisation of quantity & quality of life (QALYS) and provides theoretical basis for decision analysis trees used as means of defending decision making at a macro and meso level (Elwyn et al., 2011; Stiggelbout and de Haes, 2001).
Subjective Expected Utility Theory (SEUT)	Savage (1954)	SEUT recognises subjective element of probability. Gaming theory of probability & odds e.g. Time Trade-Off (TTO) Utilities or Standard Gamble (SG) techniques (Bowling and Ebrahim, 2001; Rosen et al., 2003; Elwyn et al., 2011) may be applied to describe utility calculations made at an individual level.
Prospect Theory or 'Framing Bias Theory'	Kahneman and Tversky (1979)	Less emphasis upon rationality presumptions. Describes how 1. individuals regularly assess potential losses and gains i.e. "Losses loom larger than gains" 2. Persons focus more on changes in their utility states than they focus on absolute utilities; 3. the framing of outcomes influences the preferences of the decision maker; 4. The estimation of subjective probabilities is severely biased by anchoring.

Appendix B Descriptive Individual Decision-making Theories

Descriptive (Individual) Decision-making Theories		
Theory	Author & Date	Key Features
Conflict Theory Model Of Decision Making	Janis and Mann (1977)	Concerned with decision making as a source of stress which elicits 1 of 5 basic coping patterns of decision making – 1. Un-conflicted adherence; 2. Un-conflicted change; 3. Defensive avoidance; 4. Hypervigilance; 5. Vigilance.
Decisional Model of Stress & Coping	Balneaves and Long (1999); Janis and Mann (1977); Lazarus and Folkman (1984)	Based upon conflict theory model & transactional framework of stress and coping.
Behavioural Decision Making Theory Theory Of Heuristics & Bias	Tversky & Kahneman (1974) Tversky and Kahneman (1981) (Kahneman and Tversky, 1996)	Limited rationality leads to use of cognitive short cuts or heuristics & human tendency to make choices which are 'good enough' rather than optimal, but may lead to systematic bias & error. 'Availability heuristic' refers to recall & reliance upon past experience to affect decision.
Ecological Rationality Model (Fast & Frugal Heuristics)	Gigerenzer and Goldstein (1996); Gigerenzer and Todd (1999)	Less convinced by 'availability heuristic' but rather suggests that decision makers refer to rules of thumb termed fast, frugal and simple heuristics i.e. 'recognition based' or 'reason – take the best option based' which evolve with experience & can be used to reach effective decisions when faced with complex information tasks e.g. 'expert opinion heuristic'.
Dual Processing Theory Heuristic-Systematic Information Processing Model (HSM)	Chaiken (1980); Chaiken and Maheswaran (1994); Chen and Chaiken (1999)	Theoretical framework for examination of patient decision making from perspective that includes both systematic and non-systematic decision processes (Steginga & Occhipinti; 2004).
Fuzzy Trace Theory	Reyna and Brainerd (1991)	There are three stages of information processing based upon a theory of reasoning and memory. 1. Representation – recognising a varying degree of precision in the way people may represent information, from exact verbatim (including surface qualities and contextual detail) to vague gist (fuzzy mental representation of the general meaning or experience). 2. Retrieval – memory limitations mean that individuals do not always retrieve and recall all information stored in a coherent manner. 3. Processing – verbatim representations fade leading to simplified reasoning at the least precise level of information encoded in memory i.e. gist
Differentiation & Consolidation (Diff Con) Theory	Svenson (1992)	Diff Con Theory (Svenson, 1992) is a process theory concerned with the importance of alternatives in reaching a sound decision – whereby an optimal decision is derived from the consideration and differentiation of various alternatives. Diff Con theory is based upon the premise that the goal of decision making is to reduce cognitive dissonance and decisional regret.

Appendix C Descriptive Collective Decision-making Theories

Descriptive (Collective) Decision-making Theories		
Theory	Author & Date	Key Features
Traditional, Paternalistic Model	Emanuel and Emanuel (1992); McKinstry (1992); Charles et al. (1999b);	Based upon principle of beneficence; endorsed professional authority, expertise & physician only choice of treatment, without eliciting the patients preferences, on basis of best interests & on behalf of submissive patient whose involvement was limited to providing consent for treatment advocated by the physician.
Interpretive Model Doctor As Agent Model 'Physician As Perfect Agent'	Emanuel and Emanuel (1992); McKinstry (1992) Gafni et al. (1998) Charles et al. (1999b);	Patient physician interaction whereby physician provides the patient with information regarding possible treatment options, endeavours to elicit patients values & preferences & on basis of this information selects treatment option on behalf of patient which they believe the patient would have chosen had they been as well informed as the physician.
Consumerist, Informed Decision Making Model	Emanuel and Emanuel (1992); Charles et al. (1999b);	Motivated by principle of autonomy and based upon consumerist interaction, promotes physician led provision of relevant information on diagnosis, prognosis, possible therapeutic interventions and the nature and probability of potential known benefits and risks of treatment options and alternatives leaving authority for the ultimate treatment decision exclusively to the patient. Alternatively, informed choice refers to instance where patient makes final decision taking physician recommendation into account.
Shared Decision Making	Charles et al. (1997); Charles et al. (1999a); Charles et al. (1999b); Charles et al. (2003)	Decision results from interactive deliberative process based upon equal participation of physician – patient, evoking two way exchange of information related to advantages & disadvantages of treatments, alternatives and patient values, beliefs & preferences and deliberation of treatment options leading to an agreed final decision.
Conceptual Framework	Charles et al. (1999a); Charles et al. (1999b); Charles et al. (2003)	Charles et al constructed framework which recognised that within each decision making approach there exists three analytical stages of treatment decision making process; 1. information transfer, 2. deliberation of different treatment options and 3. agreement regarding implementation of a treatment; which may occur simultaneously or in an iterative manner.
Integrative Model of SDM (Makoul & Clayman 2006)	Makoul and Clayman (2006)	Recognises that true 'partnership' in terms of equal sharing may not exist in truest form but rather depend upon a continuum whereby physicians may lead some discussion, patients others to culminate in a shared understanding, vision and decision making.

Appendix D Key Search Terms And Subject Headings

Key Search Terms And Subject Headings (November 2014)		
	Population	
1	Patient (?cardio*adj2patient)	Adult, Adolescent, Young Adult, Service User, Person, Recipient, Receiver, People
2	Cardiac	Card*, Cardio*
3	Arrhythmias	Tachyarrhythmia, Tachycardia, Ventricular Tachycardia, Ventricular Fibrillation, Torsades de Pointes, Anti-Arrhythmia Agents, Pacemaker,
4	Cardiac Arrest	Sudden Cardiac Arrest, Sudden Cardiac Death, Aborted Sudden Death, Heart arrest,
5	Heart Failure	Systolic Heart Failure, Cardiac Failure, Congestive Cardiac Failure
6	Cardiomyopathy	Dilated, Hypertrophic, Ischaemic
7	Congenital Cardiac	LQTS, Brugada, Romano-Ward, Jervell-Lange-Nielson
8	2 or 3 or 4 or 5 or 6 or 7	
9	1 and 8	
	Intervention	
10	Implantable Cardioverter Defibrillator Cardiac Device Therapy Cardiac Resynchronisation Therapy	Cardioverter, Defibrillator, Implantable, Insertion, Internal, Synchronise, Coordinate, Resynchronise, Pacemaker, Simultaneous, Corresponding, Shock, Device-therapy, ICD, CRT, 'Complex Cardiac'
	Outcome	
11	Decisions or Decision Making	Decide, Choice, Choose, Result, Judgement, Resolution, Assessment, Evaluation, Ruling, Opinion, Determine, View, Reasoning, Appraisal, Adopts, Selects, Elects, Indicate, Prefers, Wants, Desire, Approve
12	Decision Theory or Decision Making Theory	Model, Philosophy, Framework, Theoretical, Systems, Concepts, Scheme, Ideas, Notion, Principle, Belief, Hypothesis, Conjectures, Speculation, Assumption, Premise, Supposition,
13	11 or 12	
13	Influencing Factors	Influences, Affects, Effects, Inspires, Inspiration, Impacts, Stimulus, Encourage, Urge, Incites, Guides, Sways, Manipulates, Persuades, Induces, Prompts, Impels, Motivate, Spurs, Supports, Assists, Aids, Helps, Nurtures, Promote, Advance, Provokes, Cause, Activate, Modify, Shapes, Aspects, Reasons, Causes, Features, Characteristics, Views, Circumstances, Considerations, Elements, Qualities, Traits, Attributes, Facets, Thoughts, Deliberations, Reflections, Contemplations, Concerns
14	Accepts	Acceptance, Uptake, Receive, Agrees, Acquiesces, Assent, Accede, Assumes, Acknowledge, Allow, Approval, Commits, Endorse, Realise, Apply
15	Refuses	Refusal, Decline, Rejects, Deny, Negates, 'Turn Down'
16	13 or 14 or 15 or 16	
17	9 and 10 and 13 and 17	
18	limit 18 to 'English language' and 'year 2000 - current" Boolean operators	• or – similar, alternative concepts to broaden search • and – different concepts to narrow search • * or $ or adj2 (different across databases) eg teen$ = tees, teenager, teenager

Appendix E Medline Search String

Medline Search 25.11.14

Logged in as Alison Ketchell at University of Leeds

Ovid MEDLINE(R) 1996 to November Week 2 2014
Search Strategy:

#	Searches	Results
1	patient*.mp.	3296357
2	adult.mp. or Adult/ or Young Adult/	2675074
3	adolescent.mp. or Adolescent/	947945
4	Adult/ or service user.mp.	2389105
5	person.mp. or Persons/	59633
6	recipient.mp.	36967
7	receive*.mp.	514101
8	people.mp. or Persons/	200076
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	4980456
10	card*.mp.	689641
11	cardio*.mp.	462961
12	Tachycardia, Paroxysmal/ or tachyarrhythmi*.mp. or Anti-Arrhythmia Agents/	18734
13	Tachycardia/ or Tachycardia, Ventricular/ or Arrhythmias, Cardiac/ or tachycardi*.mp. or Ventricular Fibrillation/	52870
14	Long QT Syndrome/ or Torsades de Pointes/ or torsades.mp.	6897
15	Cardiac Pacing, Artificial/ or Pacemaker, Artificial/ or pacemaker.mp. or Arrhythmias, Cardiac/	43992
16	(sudden adj1 cardiac adj1 arrest).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	842
17	(sudden adj1 cardiac adj1 death).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	13957
18	(aborted adj1 sudden adj1 death).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	103
19	(heart adj1 arrest).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	16101
20	(systolic adj1 heart adj1 failure).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1397

21	(cardiac adj1 failure).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	5705
22	(congestive adj1 cardiac adj1 failure).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	553
23	(dilated adj1 cardiomyopathy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	12684
24	(hypertrophic adj1 cardiomyopathy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	8423
25	(ischaemic adj1 cardiomyopathy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	373
26	Tachycardia, Ventricular/ or Adult/ or Arrhythmias, Cardiac/ or Brugada Syndrome/ or Ventricular Fibrillation/ or Heart Arrest/ or brugada.mp. or Death, Sudden, Cardiac/	2429122
27	Romano-Ward Syndrome/ or Long QT Syndrome/ or romano-ward.mp. or Adult/	2392931
28	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27	2938099
29	9 and 28	2650720
30	Death, Sudden, Cardiac/ or Defibrillators, Implantable/ or cardioverter.mp. or Electric Countershock/	25740
31	(implantable adj1 cardioverter adj1 defibrillator).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	4723
32	(cardiac adj1 resynchronisation adj1 therapy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	276
33	(complex adj1 cardiac adj1 device).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	0
34	(device adj1 therapy).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	803
35	30 or 31 or 32 or 33 or 34	26405
36	(patient adj1 deci* adj1 mak*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	350
37	deci*.mp.	274624
38	choice.mp.	163142
39	Judgment/ or judgement.mp.	14601
40	Patient Preference/ or prefer*.mp.	223874
41	reason*.mp.	204453
42	select*.mp.	982224
43	choose.mp. or Choice Behavior/	38630
44	result.mp.	516771
45	resol*.mp.	282770
46	assess*.mp.	1641802
47	evaluat*.mp.	1838809
48	opinion.mp.	40723

49	determin*.mp.	1728552
50	view.mp.	132456
51	appraisal.mp. or Affect/	35551
52	adopt*.mp.	114719
53	select*.mp.	982224
54	elect*.mp.	1134495
55	indicat*.mp.	1572919
56	want.mp.	13038
57	desir*.mp.	78883
58	approve.mp.	914
59	37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58	6726556
60	(deci* adj1 theor*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1032
61	(deci* adj1 model).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1058
62	(deci* adj1 making adj1 theor*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	92
63	philosoph*.mp. or Philosophy/	23595
64	framework.mp.	99521
65	system*.mp.	1937962
66	concept*.mp.	240191
67	idea*.mp.	124219
68	principle*.mp.	110320
69	assumption*.mp.	51969
70	supposition.mp.	887
71	premise.mp.	5656
72	60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71	2392649
73	influenc*.mp.	674512
74	affect*.mp.	899222
75	effect*.mp.	3077573
76	inspir*.mp.	28400
77	impact*.mp.	490657
78	stimul*.mp.	775979
79	encourage*.mp.	45749
80	guide*.mp.	382380
81	persuade*.mp.	1001
82	prompt*.mp.	61099
83	motivat*.mp.	80835
84	Decision Support Techniques/ or Decision Support Systems, Management/ or support*.mp. or Decision Support Systems, Clinical/	5866465
85	assist*.mp.	411295
86	aid*.mp.	195517
87	help*.mp.	375031
88	promot*.mp.	552390

89	provoke*.mp.	20238
90	caus*.mp.	1224421
91	activate*.mp.	439357
92	73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91	8406276
93	aspect*.mp.	246972
94	reason*.mp.	204453
95	feature*.mp.	446373
96	characteristic*.mp.	670410
97	view*.mp.	212679
98	circumstance*.mp.	36803
99	consideration*.mp.	115328
100	element*.mp.	271353
101	qualit*.mp.	667311
102	trait*.mp.	106137
103	attribut*.mp.	171933
104	facet*.mp.	13342
105	thought*.mp.	146182
106	deliberation*.mp.	1784
107	concern*.mp.	275626
108	93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107	2917386
109	accept*.mp.	240624
110	uptake*.mp.	176661
111	receive*.mp.	514101
112	receipt*.mp.	9494
113	agree*.mp.	165736
114	acquiesce*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	216
115	assent*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	590
116	accede*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	76
117	assum*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	137249
118	acknowledge*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	14740
119	allow*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	519078

120	approv*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	77512
121	commit*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	89912
122	endorse*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	11283
123	realise*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	3585
124	apply.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	45350
125	109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124	1804589
126	refus*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	33598
127	declin*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	162014
128	reject*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	69290
129	deny.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1561
130	negate*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	3220
131	(turn adj1 down).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	163
132	126 or 127 or 128 or 129 or 130 or 131	266761
133	125 or 132	2013016
134	29 and 35 and 59	14955
135	72 and 92 and 108 and 133 and 134	305

Appendix F Full Reference List Of Studies Included In Scoping Review

Location, Journal Impact Factor And Full Study Reference *Journal Impact Factors 2017/18 https://www.citefactor.org/page/Impact-Factor-2017-2018-j.html

Location	**Impact Factor ***	**Qualitative Studies**
Sweden	1.889	Agard, A. Lofmark, R. Edvardsson, N. Ekman, I. 2007. Views of patients with heart failure about their role in the decision to start implantable cardioverter defibrillator treatment: Prescription rather than participation. *Journal Of Medical Ethics* **33**: 514-518.
Canada	2.173	Carroll, SL. Strachan, PH. de Laat, S. Schwartz, L. Arthur, HM. 2011. Patient's decision making to accept or decline an implantable cardioverter defibrillator for primary prevention of sudden cardiac death. *Health Expectations* **16**: 69-79
USA	Unavailable	Gal, C. et al. 2011. Peace of Mind: The Decision to Accept an Implantable Cardiac Defibrillator (ICD): Qualitative Findings. [Online]. pp.1-36. [Accessed 19th December 2014]. Kantor, P.B. et al. 2012. Patient decision-making modes and causes: A preliminary investigation. *Journal of the American Society for Information Science & Technology.* **63**: (7), pp.1339-1349.
USA	PhD Thesis	Lucas, L.A. 2012. The lived experience of decision-making for older adults who had an implantable cardioverter defibrillator inserted. *Dissertation Abstracts International: Section B: The Sciences and Engineering.* **73**: (5-B), p2825.
USA	3.942	Matlock, D. et al. 2010. Patient perspectives on decision making in heart failure. *Journal Of Cardiac Failure* **16**: (10), pp.1634-1644
USA	1.441	Matlock, D. et al. 2011. Patient and cardiologist perceptions on decision making for implantable cardioverter defibrillators: A qualitative study. *PACE - Pacing and Clinical Electrophysiology* **34**: pp.1634-1644
USA	1.441	Ottenberg, A.L. et al. 2014. "It's not broke, so let's not try to fix it": Why patients decline a cardiovascular implantable electronic device. *PACE - Pacing and Clinical Electrophysiology.***00**: pp.1-9
USA	1.441	Yuhas, J. et al. 2012. Patients' attitudes and perceptions of implantable cardioverter-defibrillators: potential barriers to appropriate primary prophylaxis. *PACE - Pacing and Clinical Electrophysiology.* **35**: pp.1179-87
Location	**Impact Factor ***	**Quantitative Studies**
Singapore	1.081	Chan, LL. Et al 2016 Patient Barriers To Implantable Cardioverter Defibrillator Implantation For The Primary Prevention Of Sudden Cardiac Death In Patients With Heart Failure And Reduced Ejection Fraction. *Singapore Medical Journal* **57**: (4) 182-187
Ireland	1.441	Groarke, J. et al. 2012. Deficiencies in Patients' Comprehension of Implantable Cardioverter Defibrillator Therapy. *PACE - Pacing and Clinical Electrophysiology.* **35**: pp.1097-1102.
USA	19.989	Hauptman, P.J. et al. 2013. Patient Perceptions, Physician Communication, and the Implantable Cardioverter-Defibrillator. *Jama Internal Medicine.* **173**: (7), pp.571- 577.
USA	1.441	Hazleton, AG. Sears, SF. Fiord, J. Cahill, J. Nekkanti, R. Deantonio, H. Ottoboni, L. Norton, L. Wang, P. 2013. Decisional balance among potential implantable cardioverter defibrillator recipients: Development of the ICD-Decision Analysis Scale (ICD-DAS). *PACE - Pacing and Clinical Electrophysiology* **37**: 63-72.
USA	Unavailable	Hickman R. 2010 Decision Regret In Recipients Of Implantable Cardioverter Defibrillators. *Clinical and Translational Science Conference Publication* **3**: (2) S21-S22 Hickman Jr, R.L. et al. 2012. Exploratory and confirmatory factor analysis of the decision regret scale in recipients of internal cardioverter defibrillators. *Journal of Nursing Measurement.* **20**: (1), pp.21-34.
USA	Conference Abstract	Singh, J.A. et al. 2010. Preferred Roles in Treatment Decision Making Among Patients With Cancer: A Pooled Analysis of Studies Using the Control Preferences Scale. *American Journal of Managed Care.* **16**: (9), pp.688-696.
Canada	2.66	Lewis, K.B. et al. 2014b. Making decisions about implantable cardioverter-defibrillators from implantation to end of life: An integrative review of patients' perspectives. *The Patient: Patient-Centered Outcomes Research.* **7**: (3), pp.243-260.

Appendix G Detailed Data Chart Of Scoping Review Studies

Summary Of Qualitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
1	Agard et al 2007 Sweden Journal Of Medical Ethics 1.691	Grounded theory	**Decision Process** Explore i) patients experience of consent procedure ii) their view of the role they played in DM iii) extent to which they feel able to influence decision to initiate ICD iv) current attitude towards ICD NB Agard et al (2004) paper excluded for background - reported low level of knowledge regarding condition among HF patients - patients may be satisfied with info received from Dr but still had unanswered Q's & did not always want prognostic info. Some patients accepted, some were indifferent to and some were unaware of apparent low level of knowledge.	Purposive sample 31 patients 25 (81%) men : 6 (19%) women (Last 3 were specifically selected as only 3 females included). Mean age 65 (44-79) Attending OPD with chronic, moderate to severe HF (NYHA I-III) + EF<40% + previous episode of malignant arrhythmia who had received secondary ICD. 19 no shocks, 10 experienced 1 to 5 shocks and 2 > 5 shocks	Audio taped semi structured interview 20 - 60 min (average 35min) 1 closed Q – If you had known what you know today when you were offered an ICD would you still have opted for it? Y : N : Unsure Time since ICD implant – mean 3yrs 4 months. First 13 full manuscripts transcribed but only selected parts including direct quotes of other considered essential transcribed due to limited contribution of new qualitative data!	**Approaches / Influencing Factors / Accepting Or Refusing** 3 themes :- 1) Facing a matter of fact - generally patients heeded recommendation of need for ICD. 2) An offer you cannot refuse. Patients accepted physician recommendation for ICD as having no real choice if they valued longevity. Quote displays patients view of themselves as laymen unable to have opinion of such complex medical decision Discussion 1 way Dr to Pt. **Insight Into Condition, Device Role & Function** Minimal criticism of lack of information or passive role played in DM. Participants agreed that all they needed to know was they were high risk of life threatening arrhythmia to give consent. **Physician Communication & Information Received** Did not recall discussion of alternative options; estimated of risk of potential fatal arrhythmia or expected time of survival with HF. 3 patients sought additional clarification of need for ICD. **Decision outcome** 3) Life insurance worth paying a price for - several participants had negative experiences with ICD but did not regret implant decision because device increased chance of staying alive Agard concludes a) Patients appeared not to need more info when related to life & death decisions and where no alternative option appeared to exist. b) Many desire to live longer so willing to accept technology despite poor prognosis, risks or inconvenience c) Many trust Dr judgement so readily accept recommendation.

Summary Of Qualitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
2	Carroll et al 2011 Canada Health Expectation2. 852 Also reported in 'armchair expert' in 2009	Grounded theory	**Decision Process** Pt Decision to accept or refuse primary arrhythmia ICD Carroll et al 2009 concluded that 'armchair experts' shared experiences with patients during process of waiting - thus important influential information obtained in pre implant clinic waiting room could influence patients perceptions & decision to accept ICD. Central theme was info exchange post implant with other ICD recipients. Story telling an important source of non-medical information. Post implant information which had not been included in pre implant decisions was valued as meaningful in hindsight.	Purposive sample 44 patients - 33 (75%) men & 11 - 25% women) 34 pts (27 M & 7F) accepted 10 (6 M & 4F) decline ICD. Ages 26 - 87 (mean 65 SD - 12.5). Selection criteria - >18, ability to consent, speak & read English, offered primary ICD, agree to audio tape recording. . Retired = 65%, IHD (64%) Excluded - Pts offered bi-ventricular ICD	Semi structured interview I month post implant so not to influence decision. Patients who declined interviewed at convenience within 4 weeks. Approximately 50 - 60 mins long (40mins to 2 hrs). Interview guide revised x 3 during data collection in response to preliminary analysis. e.g. 'How did you first understand that the ICD was a possibility for you?' with probes including who, where, how, when and 'How did you go about making the decision to have / not have an ICD?' with probes on influence of HCP, family, friends, others etc. 'Where did you get information prior to decision?' 'What information had the greatest impact?'	**Approaches To Decision Making** DM triggered when assimilated risk of SCD. Physician recommendation & new awareness of SCD risk motivated acceptance. Pts occupy position somewhere along a continuum between 'active & engaged' -'passive & indifferent' decision making. **Influencing Factors** Approach adopted largely influenced by 1) trust 2) social influences i.e. not wanting to harm family by sudden death & family involvement in DM 3) patient's health state. Main goal was to prolong life. **Accepting Or Refusing** Degree of activity or passivity in DM did not influence likelihood to accept / refuse ICD Contextual model developed. **Insight Into Condition, Device Role & Function** There was a general lack of understanding by patients of ICD role & function related to their condition & symptoms. **Physician Communication & Information Received** Participants did not recall receiving information related to alternatives to ICD therapy

Summary Of Qualitative Studies						
	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
3	Kantor et al 2012 Quantitative analysis of Gal et al 2011 Journal of American Society For Information Science & Technology 2.23 (Same as 'Trusting technology' paper		Aimed to establish whether relationships existed between qualitative codes & themes gleaned from patient interviews (Gal et al 2011) and demographic variables. 3 research questions: 1) Which factors or combination of factors are most salient in the patient's decision making? 2) Are there regional differences in the prevalence of the thematic codes developed by the qualitative coding activity? 3) Are differences between the thematic codes attributable to differences in demographic characteristics of respondents?		Analysed relations between frequencies of qualitatively coded data on factors that affected DM and demographic variables.	**Approaches / Influencing Factors / Accepting Or Refusing** Some regional differences (but US so not reported here); gender based differences noted - Women 2.9 times more likely than men to state 'afraid to die' (p = 0.003) which was given as main reason to accept ICD. Women 2.4 times more likely to state 'no choice' (p = 0.01) though 2.3 times less likely to state they 'needed the ICD' than men. Women 2.7 times more likely to actively confirm their decision to others Women more likely to report 'no agency', emotional reasons and Dr seen to be detailed information giver rather than authority figure as factors affecting DM than men. Men more likely to cite 'needed it' Those who described benefits of having ICD were more likely to have accepted implant because 'peace of mind' 'safety net' (both considered to be active) and 'afraid to die' (passive). Researchers conclude that those who perceive benefit from the ICD ae more likely to state psychological reason based upon security rather than the emotion of fear. Only 70 of 191 had experienced shock which was associated with reference to code related to 'save my life' - may demo impact of post implant upon recall on decision making to accept. Number of years since implant also associated difference - with 5 - 10 years post implant more likely to state 'afraid to die' as reason to accept.

Summary Of Qualitative Studies						
	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
4	Lucas 2012 PhD Dissertation Thesis Abstract in Sciences & Engineering	Phenomenology	**Decision Process** To understand lived experience of older adults DM regarding ICD implant	Purposive sample 8 patients, 6 (75%) male, 2 (25%) female >70 years mean age 84 years 3 arrhythmia, 1 HF, 1 HF + arrhythmia, 3 Don't know	Guided by theoretical lens of Paterson & Zderads (1976 / 1988) humanistic nursing Husserlian phenomenology Giorgi content analysis	**Approaches / Influencing Factors / Accepting Or Refusing** DM of older adults who had ICD implanted was influenced by 1) trust and faith in physicians decision – all participants; 2) accepting device was necessary 3) decision was easy to make (based upon perception that procedure was minor not major surgery) 4) hope and desire to live longer. Limited involvement in decision making, perceived option to be life or death, some family members involved in decision but physicians advise outweighed all else. Described a trigger then all adopt passive approach (though not described as such by Lucas) **Physician Communication & Information Received** Participants stated limited information about device role and function and what they may expect. 1 participant frustrated by lack of information, some felt information was beyond their comprehension and most failed to seek additional information.

Summary Of Qualitative Studies						
	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
5	Matlock et al 2010 USA Journal Cardiac Failure 3.065	Qualitative Descriptive	**Decision Process** To describe patients (HF) perceptions of difficult decisions and factors that influenced decision making (not specific to ICD implant but 19 had cardiac device therapy)	Purposive sample 1 centre 22 patients, 16 (73%) male, 6 (27%) female (Of 33 = 66% response) >18yrs mean age 69 years Diagnosis of symptomatic HF (ischaemic & non ischaemic cause); median EF 33%. 12 (55%) have ICD & 7 (32%) CRT	In-depth semi structured interview of 60- 90 minutes. 'Can you tell me about any important or difficult decisions you have had to make about your heart condition?' Several probes included questions regarding particular decisions related to medication, hospitalisation & getting an ICD. Patients asked to describe decision and what made it difficult. Data drawn from larger qualitative study ?? Which can't find reference to this	**Approaches / Influencing Factors / Accepting Or Refusing** Described two distinct approaches to decision making 1) 'Active' (12 pts 55%) - defined as one who described a process whereby he / she took control of DM 2) 'Passive' (10 45%) - defined as one who expressed release of control of DM. Active decision making associated with difficult decisions such as those involving ICD's, complex drug therapies & transplantation. Active participants considered & weighed up concerns related to side effects, family and overall QOL; they required time to reflect & wanted second opinion. Passive decision makers did not identify a difficult decision, described influencing factors as trust in God & the physician and the power of the physician. Some passive DM believed all medical therapies to be helpful where as others disengaged from medical care altogether.

Summary Of Qualitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
6	Matlock et al 2011 USA PACE 1.25	Qualitative Descriptive	**Decision Process** To understand patient & cardiologist perception of decision making for ICD. Specifically to explore how benefit & risk of ICD was discussed.	Purposive sample 2 implant centres 11 physicians (academic / non-academic cardiologists & general cardiologists / electrophysiologists) 20 patients, 12 (60%) male 8 (40%) female Mean age 59 years (34 – 72) Primary ICD 14 (70%) accept & 6 (30%) decline Biventricular pacing excluded because potential associated improvement in HRQL Mixed race	In-depth, semi structured interviews using broad, open ended questions. 3 question guides developed for patient with ICD; patient who declined & cardiologist. Questions based upon health belief model and domains of patient centred care, decision quality & decision conflict. Some questions modified from research on cardiac stents and decision aid development and some questions addressed inappropriate shock therapy and deactivation at the end of life. Interview schedule included in paper.	**Approaches / Influencing Factors / Accepting Or Refusing** Patients who chose ICD - 3 themes 1) Desire to avoid death 2) Need to follow physicians advice 3) Discovery of risks post implant Many accepted ICD on physicians advice without questioning benefit and risks. Patients who refused ICD - 1) Considered ICD to be unnecessary or believed risk of SCD did not apply to them 2) Perception that burden outweighed benefit 1 patient considered trade-off between dying quickly & living longer with progressive HF – member checking with 5 others confirmed that they had not considered this **Physician Communication & Information Received** Some ICD recipients reported not knowing about side effects until after device implant or when they experienced side effects. Cardiologists communication with ICD patients – 3 themes 1.Considerable variation existed in approach to patient centeredness and communication. 2 main approaches - beneficent paternalistic and patient centred, shared approach. **(Approach)** 2. Cardiologists influenced by benefits presented in published guidelines 3. Discussion revealed clear hierarchy in which cardiologists emphasised benefits but emphasis of risks varied greatly Cardiologists adherence to guidelines appeared to inhibit SDM. Marked difference in discussions surrounding ICD suggests need for improved process in ICD DM.

Summary Of Qualitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
7	Ottenburg et al 2014 USA PACE 1.25	Qualitative Descriptive	**Decision Process** To examine perspectives & experiences of patients who decline implantation of a ICD	Purposive sample identified from SCA register & EF ≤ 35%. 13 (of 84 – 15% response) 11 (85%) male 2 (15%) female. (20 invite non responders; 24 declined to participate; 13 stated not had consultation; 9 had consented to ICD; 3 DNA focus group & 2 decline due to hearing impair or physical ill health) Median age 65 (range 44 - 88). All white & 10 married Declined primary ICD	3 focus groups of 5, 3 & 5 patients - semi structured interview - Initial questions 1) asked patients to explain personal and health histories. 2) Patients asked about their medical eligibility for a device and how the subject was approached by their health care team. 3) Several questions asked patients to pinpoint the people, values, or other factors that influenced their decisions. 4) Later questions explored patients' advance care planning and the advice they would give to other patients, families, or clinicians	**Approaches / Influencing Factors / Accepting Or Refusing** Six major themes 1) 'Don't mess with a good thing' - focused upon current health rather than health trajectory. Importance of living now as opposed to longer in the future i.e. quality rather than quantity. Benefit not considered to be worth risk of side effects. Acceptance of inevitability of death 2) 'My health is good enough' – preferred to wait for health improvement before committing to device, affected by experience and advise of others, accepted current health state as sufficient and acknowledged risk of declining 3) 'Making independent decisions' - valued collecting information and not feeling pressured by clinician or family to accept, decision made independently though acknowledged others opinion 4) 'It's your job, but it's my choice' – considered ICD recommendation to be physicians duty but did not feel overtly coerced, though perceived limits to time to decide created stress for some Decliners described as collecting as much info from Dr and others as possible to make informed decision & needed time to analyse and reflect - thus active DM. Patients who declined considered clinicians recommendation of need for device to be less influential than the way they felt - suggests preference for quality rather than quantity of life. Patients considered DM to be a process not one off episode therefore some would re deliberate in future. **Physician Communication & Information Received** 5) 'Gaps in learning' – identified gaps in knowledge, participants keen to have all information, suggested they should be empowered to ask clinicians more & physicians could explore how best to educate patients 6) Clinicians perspectives refers to agreement between patients view of refusal and what clinicians had documented in medical notes as reason for non-implant. Clinicians appeared to be unaware that patients lacked knowledge of purpose & function of ICD

Summary Of Qualitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
8	Yuhas et al 2012 USA PACE 1.25	Grounded theory	**Decision Process** To explore patients' attitudes and perceptions of ICDs to better understand potential patient-related barriers to appropriate utilization	Purposive sample 3 sites - records of patients visiting 3 OP cardiology clinics (June 2009–January 2010). 25 patients, 18 (72%) male, 7 (28%) female Mean age 69± 3 years (35-94). 12 accept & 13 decline 474 patients with ejection fractions ≤35%, of which 72 met criteria for primary ICD placement - 71 invited to participate. 12 not reachable, 2 deaf, 7 had ICD & 24 refused, 1 interview not recorded 100% Caucasian.	25 semi structured, open ended interview by telephone. Interview prompts available in paper – (may consider replicating some of these questions)	**Influencing Factors / Accepting Or Refusing** Five major themes emerged: 1) Personal risk - Patients who refused ICD referral demonstrated a lack of insight into their own risk potential for SCD 2) Strength of recommendation - Patients who accepted ICD referral perceived that this was strongly recommended (prescribed not offered) by physicians; those refusing did not (weak recommendation or elective). 3) Concerns over recall, malfunction, and surgical risk were common in both. 4) Feelings regarding invasive life-prolonging interventions played an important role in ICD referral refusal – suggests quality rather than quantity No significant demographic or clinical difference between participants & non participants and between acceptors and decliners **Physician Communication & Information Received** 5) Inaccurate perceptions of ICD-related risks and lifestyle limitations. Acceptors often reported these perceptions being addressed by their physician. **Insight Into Condition, Device Role & Function** Acceptors and decliners had reasonably good understanding of purpose & function of ICD

Summary Of Quantitative Studies						
	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
9	Chan et al 2016 Singapore Singapore Medical Journal	Retrospect cross sectional survey	**Decision Process** To determine if demographic or social factors influenced patients decision to decline	Convenient sample from OPD clinics or admission / referral to cardiology wards 1 implant centre 240 patients, 202 (84%) male, 38 (16%) female Mean age 61.2 years (standard deviation [SD] = 9.7 years Excluded secondary prevention or re-implantation All had declined device for primary prophylaxis against SCD in HF	Face to face interview – structured. Questionnaire designed by researchers based upon previous surveys, local practice and known patient issues	**Insight Into Condition, Device Role & Function** Perceived consequence of heart failure said to be stroke (42%), SCD (28%), MI (17%), don't know (14%). 68% believed medication could prevent SCD, 16% believed exercise and diet could prevent SCD. Only 8% understood SCD preventative role. When asked about ICD function 52% correctly answered SCD prevention, 48% were not aware of SCD preventative role. Most feared consequence of heart failure was being bed bound (37%), breathlessness (30%), SCD (17%), chest pain (8%), don't know (8%). All believed ICD would restrict life style including inability to do heavy lifting (30%), problems with electrical devices (17%), flying (10%), swimming (12%), sexual activity (5%). Chan conclude that limited consultation time, language barriers, deep seated beliefs that contradict physician advise could explain lack of understanding **Approaches To Decision Making / Accepting Or Refusing** 98% relied upon physician information only. 2% sought additional information from internet (5%) and publications (10%) Most (61%) believed they were most important person influencing decision, 15% felt that Dr played most important role. All refused because: cost (27%), invasive nature of procedure (24%), fear of complications (11%) advancing age (9%). Traditional factors associated with acceptance of more aggressive treatment i.e. younger, disease duration, educational attainment, salary were not evident. Strength of physician recommendation did influence decision i.e. not strong recommendation = refusal. Chan conclude this may have been associated with passivity in information gathering. **Decision Outcome** 65% did not regret decision, remaining unwilling to accept, 35% might agree to ICD in the future. Those most likely to reconsider were employed (possible financial reasons), feared SCD the most and acknowledged ICD preventative role

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
10	Groarke et al 2012 USA PACE 1.25	Retrospectcohort study - cross sectional survey	**Knowledge & Understanding** To investigate extent to which ICD patients understand & retain information and determine expectations of ICD therapy	Random selection from hospital register of ICD recipients. 2 implant centres. 75 patients, 62 (83%) male, 13 female (17%) Median age at time of ICD implant 64 years (standard deviation [SD] = 9.4; range: 29–82 years), No exclusion criteria. 69 ICD - primary or secondary prevention. 6 CRT patients	Telephone interview – open and closed semi structured questionnaire designed by researchers Median interval from implant to interview 3 years (SD = 1.9; range: 0.1–9.0 years),	**Insight Into Condition, Device Role & Function** 83% (62 of 75) claimed to understand reason for ICD implant. Sub group of 25 asked to explain reason for implant in own words - no patient suggested arrhythmia termination, 6 (24%) inferred arrhythmia related reason; 7 (28%) inferred heart failure, 7 (28%) gave various reasons including reducing risk of 'heart attack', 5 (20%) unable to state a reason other than physician recommendation. Excluding CRT patients (n=6), ICD recipients incorrectly believed that the device would improve of cardiac function (42 of 69 : 61%), breathing (36 of 69 : 52%), exercise capacity (35 of 69 : 50%) and reduce risk of heart attack (45 of 69 : 65%) or stopping breathing (33 of 69 : 48%). **Physician Communication & Information Received** Shock recipients, 60% (12 of 20) felt poorly prepared for shock therapy. Of patients who experienced device-related complication, 83% (10 of 12) reported feeling inadequately forewarned of complications. Despite pre implantation education, patient comprehension of risks & benefits of ICD therapy is poor and expectations of ICD therapy may be inappropriate. **Approaches To Decision Making / Accepting Or Refusing** 5 of subgroup of 25 (20%) stated physician recommendation as reason for implant. 35 of 75 (47%) suggested Dr decision, 19 (25%) stated patient decision & 21 (28%) stated joint decision. 40 (53%) preferred Dr to make decision and 35 (47%) desired all relevant information to facilitate own decision. 26 (35%) reported feeling frightened when informed of requirement for ICD. **Decision Outcome** 93% (70 of 75) were satisfied with decision to accept ICD therapy. Only 12% (9 of 75) believe they will want to inactivate therapies in setting of terminal illness.

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
11	Hauptman et al 2013 USA Journal American Medical Association (JAMA) Internal Medicine 1.699	Retrospect Compare	**Knowledge & Understanding** To examine patient-physician communication at the time the decision is made to implant an ICD. To compare discussions gleaned from patient focus group interview with findings from 'standardised patient interviews'. Focus groups to explore (1) the effect of ICD placement and downstream events on patient acceptance of device, (2) patient's evaluation of communication about risks & benefits during pre-implantation discussions,(3) patient expectations.	Selected by national health care marketing research company. 3 geographical areas. 41 patients, 20 (49%) male, 21 (51%) female. Mean age 61.4 SD 14.7 yrs, 16 (40%) > 70 years old & 9 (22%) < 50 years Indication for and device type unclear though 12 had primary ICD. 20 (49%) patients experienced 2 or more device procedures eg upgrade, advisory or recall, generator change Exclusion – no previous SCD experience pre ICD implant or from same cardiology practice as another participant. 11 cardiologists from 2 urban locations each interviewed 2 simulated patients.	8 patient focus groups Topic guide to structure audio recorded discussions of approx. 120 minutes. Patients asked: 1. To rate degree to which they felt informed before the implant procedure 2. To estimate number of patients of 100 who would be saved by the ICD. 3. About range of ICD-related experiences. 4. To estimate degree to which they felt informed before the implant procedure on a scale of 1 to 10 (1 indicates "not at all informed," and 10 indicates "I had all the information I needed or wanted"). Time since ICD implant 1 to 11 years. Simulated patients prepared and consultation video-taped and observed through 1 way mirror. Data abstraction tool developed to analyse interviews	**Insight Into Condition, Device Role & Function** The mean (SD) estimated number of patients out of 100 who would be saved by the ICD was 87.9 (20.1). **Physician Communication & Information Received** Focus groups : Mean (SD) rating of preparedness for 39 patients was 5.7 (3.2) out of 10 at the time of the implant procedure and during the patient focus group meeting. 2 patients indicated little interest in detailed knowledge of risks. 33 (80%) did not recall discussion of peri procedural risk or post implant complications. Recalled limited discussions on QOL issues which focused upon fact that ICD would have no lifestyle effect. QOL measures not used pre or post implant. Pre implant mention of anxiety or depression was infrequent. Participants reported most interactions were brief & decisions made quickly with little time to understand the implications. Some were discharged home to consider decision. Unanimous agreement that gained knowledge of benefits and risks post implant. The SP interviews focused medical history & procedure-related processes in context of medical benefit of ICD. Psychosocial history obtained in 11 of 22 SP interviews. Unexplained medical jargon used in 15 of 22 encounters. Primary emphasis upon prevention of SCD & rarely study data of prevalence of actual life-saving shocks, no who require shock or risk of death despite shocks. >17 of 22 interactions failed to address, minimised or denied QOL issues and long term consequences including risk of anxiety, depression, inappropriate shock therapy or device advisories. Psychosocial implications largely limited to social issues such as security devices. Risk of anxiety mentioned in 1/3 of interviews depression not mentioned. Peri procedural complications such as bleeding (11 of 22 50%) & infection (10 of 22 45%) most often noted but more major ones such as pneumothorax, lead dislodgement noted less often. Inappropriate shock discussed in 15 of 22 (68%) interviews, though risk minimised in 11 of 15 cases. Patients largely uniformed and overly optimistic about future expectations with ICD. Patient group consistently note inadequacy of information received pre implant and inattention paid to psychosocial issues post implant **Approaches To Decision Making / Influencing Factors** When ICD deemed urgent, pts particularly overwhelmed by pace of DM. Older participants frequently mentioned that they deferred the decision to family members. Many struggled with competing view of ICD as security net & source of physical & psychosocial discomfort.

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
12	Hazleton et al 2014 USA PACE 1.25	Prospect	**Knowledge & Understanding** 2 stages 1) To design a measure - the ICD - Decision Analysis Scale (ICD-DAS) to assess importance of ICD pros and cons factors that may influence DM. 2) Examine discriminant validity of measure from existing psychological measures & test predictive validity of proposed ICD measure on behavioural intention to accept ICD. Literature review alludes to HSM & framing and utilises Svenson's Differentiation & Consolidation theory as framework for the study. 2 parts - 1) Initial design of (ICD-DAS) assessment involving administering ICD-DAS to potential ICD recipients for scale development & validation. 2) to conduct empirical test of instrument through patient assessment & factor analysis.	Phase 1: 2 cardiologists, 1 electrophysiologist & 1 cardiac psychologist. Phase 2: 2 Implant centres. 103 patients 67 (65%) male & 36 (35%) female. Patients were mean age 54.86 (standard deviation [SD] = 9.4; range: 19–90 years), Met criteria for ICD, English speaking, >18yrs. Mixed race, majority married (53.3%)	ICD Pros & Cons scale devised from literature review of risks & benefits of ICD = list of 121 potential pros and cons of ICD therapy. Theory-based grouping of variables allowed for reduction of total items to 24. Semi structured qualitative interviews with providers to: 1) assess face validity of refined list pertaining to patient choice of the ICD 2) to adjust 24 items to help best describe & represent underlying constructs. Reviewers rated (yes/no) of the 24 items & provided suggestions for adjustments to particular items. Amendments were made to the wording of items to satisfy each reviewer. Potential ICD recipients completed ICD-DAS, MOS SF-12, HAD scale, Religious Health Fatalism Q, C-MHLC scale & demo data form.	**Decision Aid** Patients rated a number of items as 'very important' or 'extremely important', most items rated as 'relatively important' and some as 'not important' - examples are given in paper. Factor analysis was performed to evaluate inter item relationships & subsequently, identified subscales; additional psychosocial measures were used to predict the ICD decision. A two-factor measure for ICD decision making was established with two subscales: ICD Pros and ICD Cons. The subscales have high internal consistency and were strong predictors of intent to choose an ICD. Other psychosocial measures were not significantly predictive of ICD Choice, yet simultaneous entry of ICD Pros and Cons subscales resulted in a significant increase in R2, F(2, 59) =19.36, P < 0.001. The full model was significantly greater than zero, F(11, 70) = 5.017, P < 0.001, R2 = 0.48. The final version ICD-DAS comprised of 22 items, with two factors labelled ICD Pros and ICD Cons. The factors (and total scale) were found to have high internal consistency & factors were strong predictors of intent to choose ICD. A greater percentage of overall variance was seen in ICD Cons subscale, consistent with research indicating that most patients are more affected by risks than benefits. A set of general psychosocial measures were not significantly predictive of ICD Choice, suggesting that the ICD-DAS is a more efficient and accurate predictor of patient intent to choose the ICD. Hazleton et al - ICD – DAS provides empirically tested & clinically useful pros & cons scale to help patient decision making. It utilises Diff Con Theory (Svenson) to include patients more fully in healthcare - though it is not immediately obvious in paper how it really supported the study.

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
13	Hickman 2010 Hickman Jr et al 2012 US Journal Of Nursing Measure. Impact factor not available	Cross Sectional Descript	**Decision Outcome** To determine the associations between clinical and psychological factors and decision regret in ICD recipients (2010) (Abstract only) Second paper based upon 2010 study aimed to assess validity & reliability of Decision Regret Scale as a measure of decision regret in ICD patients (2012)	Convenience sample 1 implant centre 109 recipients of an ICD implanted during 2006-2008 at an academic medical centre in Northeast, Ohio	Structured telephone surveys 1. Abbreviated Miller Behavioural Style Scale to measure informational coping style 2. Control Preferences Scale to assess decision making preference 3. Medical Outcomes Study Short Form (SF)-12 to assess quality of life 4. Profile of Mood States Short Form to capture post decision emotional status 5. Decision Regret Scale (DRS) - 5 item instrument to capture individuals regret associated with a healthcare decision. Clinical data such as indication for ICD, shock status, and demographic characteristics gleaned from medical records	**Decision Outcome** The amount of decision regret (no regret vs. regret) was not associated with demographic or clinical variables, such as the ICD indication (primary vs. secondary prevention) or ICD shock status (no shock vs. shock); while adjusting for the recipient's age, gender and number of post-decision complications. Informational coping styles, monitoring and blunting, were significant predictors of decision regret; while adjusting for clinical and psychological variables. Tailored communication interventions based on assessment of patient's informational coping style may reduce decision regret and support patient's engagement in subsequent health seeking behaviours. In 2012 further exploratory & confirmatory factor analyses, internal reliability consistency (= 0.86) and discriminant validity established DRS as valid & reliable measure of decision regret in ICD recipients. Researchers concluded that the DRS was a psychometrically sound instrument for assessing decisional outcomes of ICD recipients

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
14	Singh et al 2012 USA Circulation (Conference abstract only)	Compare	**Knowledge & Understanding** To explore factors leading to acceptance or refusal of device implant for primary prevention	Random selection 50 Mean age 62+11 yrs. 54% Caucasian (C), 36% African American (AA), 10% Asian (A). 29 pts (58%) accepted an ICD 21 pts (42%) refused, the "no ICD" group. 50 of 533 HF patients identified with EF <35% -mean EF was 24+7%	Prospective standardized interview and use of a 1-10 rating scale	**Insight Into Condition, Device Role & Function** Comparison of ICD pts to no ICD pts – 1. Both groups understanding of HF was poor, 4.5 on a scale of 1-10. The no ICD pts had less understanding of ICD purpose p<0.0003 , were less likely to have been given written ICD information (71 vs 38%, p=0.02) and were less likely to recall a recent discussion on the topic of ICD's (52%). **Accepting Or Refusing** 2. Both groups quality of life was more important than quantity 7.7+3 out of 10. 3. Although 93% were Christian, religious belief (3.3+3 out of 10) and cultural values (3.2+3 out of 10) did not play a major role in decision making. 4. Both group felt they had great access to health care resources and physicians (8.5+2 out of 10). 6. Women were less likely to be married 26 vs 63%, p=0.02. A pts were younger than C, 56 vs 66 years, p=0.04. AA pts had less understanding of low EF vs C, p=0.02 and trended towards having less access to best medications p=0.1 No significant differences in patient demographics, cardiac risk factors, HF medications or baseline lab work. **Decision Outcome** 5. Only 2 (7%) of ICD pts would not accept an ICD again, while 18 no ICD (86%) pts would now reconsider implant, p<0.001 Quantitative study suggests that underutilization of ICD's for primary prevention of SCD may in part be related to limited communication and poor understanding of HF, sudden death, and the devices. Majority of patients initially refusing a device are willing to reconsider implant. These findings, with further validation, offers a potential approach to improving ICD underutilization in high risk patients.

Summary Of Quantitative Studies

	Author; Date; Location; Publication; Impact Factor	Study Design	Study Aims	Sample Size; Selection Criteria	Data Collection Method	Key Findings
15	Lewis et al 2014 Canada The Patient: Patient Centred Outcomes Research 1.957	Integrative Review	**Decision Process** Explore patient's DM experiences from decision to implant to consideration of deactivation at end of life		Whittemore & Knafl 5 Steps - data collected 2000 to 2013. Research based upon theoretical framework - Ottawa Decision Support Framework which states that patients & support networks unresolved decisional needs affect decisional quality.	**Approaches / Influencing Factors / Accepting Or Refusing** Of 354 potential citations - 25 papers included. Trajectory of key decision points were whether or not to initiate ICD therapy, replace battery & deactivate at end of life. 3 common themes from patient perspective – 1) Influence of patient - practitioner consultation on knowledge 2) patients DM preference 3) desire to live. Participants expressed mixed preference for desire to be involved in decisions. Decisions particularly difficult due to life & death trade off. **Insight Into Condition, Device Role & Function** Pt's with ICD often misunderstood functionality or over-estimated benefit. **Physician Communication & Information Received** Lewis et al recommend clinicians better support patients by 1) verifying understanding 2) eliciting preferences 3) promoting shared decision making

Appendix H Scoping Review Study Quality Appraisal

Summary Of Qualitative Studies

	Study	MMAT Score	Lewis MMAT	Strengths	Limitations
1	Agard et al 2007	75%	75%	Direct quotes used to demonstrate how categories determined	No detail of interview guide or prompts other than one closed question Mainly male 81% participants Secondary ICD only Retrospective - interviews up to 3 years 4 months post ICD may affect recall of information originally given Patient : Dr consultation and information giving may have differed between participants. Numerical analysis of the closed ended question is not provided. Restricted transcription to 13 may have limited full immersion and saturation in the data - could have missed key elements.
2	Carroll et al 2011	100%	100%	Participants recruited from 3 implant centres Purposive sample (n=44), mixed race, 33 male and 11 female Interviews at least 1 month post implant to avoid influencing decision and within 1 month for those who declined Interview guide described and revised 3 times during data collection Data saturation achieved Analysis and interpretation evident and supported by direct passages from participants with reference to gender, age and device acceptance included Conceptual model development (though quite complicated) Different methodology to explore and compare patients HRQL / behaviours who accepted / declined ICD actively & passively recommended. Could also assess decisional satisfaction & regret after implant.	No detail of interview guide or prompts other than one closed question Primary ICD only Minimal analysis of demographic e.g. gender, age, racial influences or impact of non-medical information upon decision Brief mention that decliners considered age and co-morbidity as opposed to accepters. Some quantitative comparison and attempt to distinguish between acceptance and refusal influences / comments may have been useful e.g. did trigger, source of info, age, time taken to make decision etc. impact upon / associate with ultimate decision?

Summary Of Qualitative Studies

	Study	MMAT Score	Lewis MMAT	Strengths	Limitations
3	Gal et al 2011	Mixed Methods 50%		Participants recruited from 3 implant centres Participants selected on basis of cardiologists invitation therefore researchers had no knowledge of medical background, indication or type of device - no intention to explore DM against condition context. (Interest lies in human acceptance of technology in lives & healthcare). Detailed description of patient narratives and refer to direct quotes to support coding. Detailed appendix available outlining code and definitions supported further with reference to patient quotes. Inter coder reliability described	Indication and device type unclear Exclusion of patients who refused ICD (interested in acceptance and refusal!) Predominantly white No indication whether patient had experienced any benefits from device Shock therapy noted but not experienced by 61% Telephone interview and therefore potential impact of different interviewer styles may have led to geographical difference in some responses States open ended questions though very specific and structured for grounded theory approach Researcher conceptualisation of DM as an individual rather than group process (though they consider active / passive DM) Retrospective - interviews mean 5.39 years post ICD may affect recall of information originally given Discussion / conclusion largely repeats results rather than putting results in context of previous studies.
	Kantor et al 2012		50%	Quantitative analysis of acceptance and refusal based upon demographic difference (focus on regional and gender difference) Clear and open description of findings. Accept that they cannot provide statistical significance but clearly describe how they made their inferences. Discussion section attempts to explain and put in context findings arising from analysis	Influenced by limitations above

Summary Of Qualitative Studies

	Study	MMAT Score	Lewis MMAT	Strengths	Limitations
4	Lucas 2012	50%		Clear and open description of findings with reference to participant responses to support themes	Indication and device type unclear Small sample, all white, Caucasian and 75% Jewish No indication whether patient had experienced any benefits from device Shock therapy noted but not experienced by 62.5% Retrospective - interviews 1 – 16 years post ICD (50% > 6 years) may affect recall of information originally given Very brief discussion / conclusion section which largely repeats results, refers to very limited number of previous studies referred, fails to allude to previous work and theory on impact of age upon healthcare treatment decision making
5	Matlock et al 2010	100%	75%	Direct quotes support thematic analysis and places findings in context of previous work. Discussion alludes to narrative review by Say et al 2006 on characteristics of active & passive decision makers. Decisional Control Preferences Scale recommended for future research.	Participants recruited from 1 implant centre Non representative sample of HF patients – concerned with what constituted difficult decisions and approach to DM Interview semi structured not open ended but did elicit some patient experience Small sample didn't allow quantitative comparison of demographic data and type of DM 12 had ICD and 7 CRT though no attempt to analyse decision style in light of indication or device type
6	Matlock et al 2011	100%	100%	Interview schedule included Member checking to affirm findings Direct quotes support thematic analysis, a descriptive model illustrates Dr : Patient interaction during ICD DM and findings placed in context of previous work.	Data saturation among decliners not reached due to small sample
7	Ottenberg et al 2014	100%		Direct quotes support coding and thematic analysis.	Small select sample, all white, all Christian and only 2 women. Selection bias on basis of willingness to participate
8	Yuhas et al 2012	100%	100%	Participants recruited from 3 implant centres Interviews conducted pre implant early after consultation Interview questions and prompts are included Good use of direct quotes to support thematic analysis Data saturation achieved	Primary ICD All Caucasian and 72% male. Selection bias on basis of willingness to participate

Summary Of Quantitative Studies					
9	Chan et al 2016	75%		Questionnaire available Primary prevention only Decliners only	Researcher developed semi structured questionnaire – validity and reliability unconfirmed. Mainly male 84% participants
10	Groarke et al 2012	100%	100%	Participants recruited from 2 implant centres. Random selection from ICD recipient lists enhanced representativeness. Questionnaire available	Researcher developed semi structured questionnaire – validity and reliability unconfirmed. Relatively small sample (n=75) for quantitative study Mainly male 83% participants Retrospective - interviews up to 3 years post ICD may affect recall of information originally given Responses may reflect general improvements in other symptoms and perceived level of well being Educational level and assessment of health literacy is not reported. All device types included however no further analysis of potential influences eg demographic, indication, social support upon answers
11	Hauptman et al 2013	50%	50%	Participants recruited from 3 geographical areas Heterogeneity of patient group a positive feature Random sampling All device types included Patient physician interaction video taped and observed Data abstraction tool available	Researcher developed semi structured questionnaire – validity and reliability unconfirmed Small sample in both groups (n=41 patients & 22 interactions) Retrospective – interviews1 to 11 years post ICD may affect recall of information originally given Simulated patients therefore hypothetical situation Observed interaction could lead to Hawthorne effect Structured data abstraction tool used to analyse simulated patient : physician interaction loosing potential to capture verbal : non verbal information Indication and device type unclear (12 primary ICD) therefore no further analysis of potential influences eg demographic, indication, social support upon answers
12	Hazleton et al 2014	75%		Participants recruited from 2 implant centres Convenience sample (n=104), mixed race, 67 male and 36 female Potential ICD recipients interviewed pre implant Range of valid psychosocial measures (HAD, MOS SF-12, used alongside ICD-DAS	Indication suggests primary prevention ICD though not entirely clear Diff Con Theory (Svenson, 1992) not explicitly applied to study

Summary Of Quantitative Studies					
13	Hickman et al 2010 & 2012	75%		Used standardised, valid and reliable data collection instruments Primary and secondary devices included	Participants recruited from 1 centre and 52% approached refused to participate. Mainly white, male Caucasian Decision regret of decliners not included No analysis of decision regret by indication / device type
14	Singh et al 2012	Abstract only		Random selection of 50 of 533 HF patients, mixed race Compared acceptors 29 (58%) with decliners 21 (42%)	1 implant centre No details given regarding prospective standardised interview and 1 – 10 rating scale No detail regarding time since consultation or implant Conference abstract therefore limited information to assess methodological quality
15	Lewis et al 2014			Integrative Review	

Appendix I Strand 1 Questionnaire

Participant Id No:

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HOW DID YOU REACH YOUR DECISION REGARDING PRIMARY PREVENTION CARDIAC DEVICE (ICD or CRT) THERAPY?

Thank you for agreeing to complete this questionnaire which should only take approximately 15 to 20 minutes of your time. It is composed of 6 sections each with a number of tick box answer questions. Each section includes a brief explanatory note on how to address each question. Please answer as fully as you are able and feel free to make any additional comments alongside your tick box answers.

Please return the questionnaire in the enclosed pre-paid envelope to:
Alison Malecki-Ketchell
Room 2:17, Baines Wing
School of Healthcare
University of Leeds
Woodhouse Lane
Leeds LS2 9JT

Alternatively you may complete the questionnaire on line by visiting:
https://leeds.onlinesurveys.ac.uk/cardiac-device-decision-making

You can complete the online questionnaire in one sitting or may elect to save and close the survey to return to at a later stage. You will receive notification of survey completion once you have clicked ‘finish’.

If you require any further information or would like to discuss any issues regarding the study please don’t hesitate in contacting Alison (details above)

Section 1 - Please provide the following details:

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Forename:

Surname:

Consultant:

First Language:

	Please confirm agreement to this statement by
I give permission for Alison Malecki-Ketchell to access my medical records if necessary to glean supplementary information regarding my device solely for the purposes of this research project	

Please continue to Section 2

Section 2 - Demographic Details

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Please tell me a bit about yourself by placing a tick in the boxes which apply:

Q. 1	**What is your age (years)?**

Q. 2	**Gender**	Male		Female	

Q. 3	**Religion**	Christian		Jewish	
		Muslim		Sikh	
		Buddhist		Hindu	
		None			
	Other (please specify):				

Q. 4	**Ethnicity**	White (British)		Asian	
		Black			
	Other (please specify):				

Q. 5	**Relationship**	Single		Divorced / separated	
		Married/Civil Partner		Widow / er	
	Other (please specify):				

Q. 6	**Social**	Live with next of kin		Live alone – friends	
		Next of kin nearby		Minimal	
	Other (please specify):				

Q. 7	**Education**	CSE / ‘O’ levels		Bachelors degree	
		‘A’ levels		Masters degree	
		Certificate / Diploma		PhD	
	Other (please specify):				

Q. 8	**Employment**	Employed /		Unemployed	
		Retired		House worker	
		Seeking employment		Volunteer	
	Other (please specify):				

Q. 9	**Occupational**	Student		Clerical	
		Unskilled Manual		Managerial	
		Semi-skilled Manual		Professional	
	Other (please specify):				

Please continue to Section 3

Section 3 - Medical History

It would be helpful to know what a bit about your health and cardiac (heart) history **Please tick all the boxes that apply:**

Q. 10	Do you or have you ever experienced any of the following conditions?			
		Yes	No	Don't know
	A heart attack			
	Angina			
	Heart failure			
	High cholesterol			
	High blood pressure			
	Diabetes			
	Cardiomyopathy			
	If you answered yes to cardiomyopathy and you know what type (eg dilated, hypertrophic), please state:			
	An inherited / congenital cardiac condition	Y	N	DK
	If you answered yes to an inherited / congenital cardiac condition and you know what type (eg LQT, Brugada, Fallot's etc), please state:			
	A fast heart rate / rhythm	Y	N	DK
	If you answered yes to a fast heart rhythm and you know what it is (eg VT, AF, SVT etc), please state:			
	A slow heart rate / rhythm	Y	N	DK
	If you answered yes to a slow heart rhythm and you know what it is (eg sinus bradycardia, heart block etc), please state:			
	Other (please specify):			

Q. 11	Do you have a family history of heart rhythm problems?		
	Yes	No	Don’t know
	If you answered yes and you know what it was and / or who it affected please state:		

Q. 12	To what degree, if any, do your symptoms affect your daily activity? **Please tick one:**	
I	Normal physical activity without symptoms	
II	Slight limitation of physical activity	
III	Marked limitation of physical activity	
IV	Symptoms at rest	

Q. 13	Please briefly describe or list your main symptoms at the time you were recommended for an ICD or CRT:

Please continue to Section 4

Section 4 - Cardiac Device Therapy

If possible please explain which device you have been recommended, when, why, what and by whom it was discussed.

Please tick all the boxes that apply:

Q. 14	Which device?	
	Implantable cardioverter defibrillator (ICD)	
	Cardiac resynchronisation therapy (CRT-P) Pacemaker function only	
	Cardiac resynchronisation therapy (CRT-D) Pacemaker and defibrillator function	
	Don’t know	

Q. 15	When was a device first suggested to you?			
	Within the last month		More than 6 months ago	
	Within the last 6 months		Don’t know	

Q. 16	Why was it recommended?	
	To prevent or treat fast heart rate / rhythms	
	To improve your heart failure symptoms	
	Both prevent / treat fast heart rate and improve heart failure symptoms	
	Don’t know	
	Other (please specify):	

Q. 17	Were any of the following alternative treatment options offered or discussed **instead of ICD or CRT** with you? Please tick all that apply	
	Drug therapy for fast (tachycardia) heart rate / rhythms	
	Drug therapy for heart failure symptoms	
	Ablation (atrial or ventricular)	
	Percutaneous Coronary Intervention (PCI) / Angioplasty	
	Open heart surgery (please specify eg CABG, valve replacement etc)	
	Alternative cardiac device (please specify eg bradycardia pacemaker)	
	Heart transplant	
	No alternative treatment options were discussed with me	
	Other (please specify):	

Q. 18	Did you have the opportunity to discuss and consider any of the following issues? Please tick all that apply	
	The benefit and risk of accepting the device	
	The benefit and risk of refusing the device	
	Alternative treatment options	
	Potential physical complications during and after device implantation eg infection, lead problems etc	
	Any psychological / emotional concerns you may have had related to device therapy	
	Social issues related to device therapy eg driving, flying, sexual activity, swimming, sport participation etc	
	Impact of the device upon your work and / or home related activities	
	No opportunity to discuss any of the above	
	Other (please specify):	

Q. 19	Please state what, if any, concerns you had regarding accepting the device:

Q. 20	Please state what, if any, concerns you had regarding refusing the device:

Q. 21	Who recommended it? Please tick all that apply and include the doctors name below if you know it	
	GP	
	General medical consultant	
	Cardiology consultant	
	Heart failure specialist consultant	
	Electrophysiology (heart rhythm) consultant	
	Cardiac inherited / congenital conditions consultant	
	Other (please specify):	
	Please state doctors name if known:	

Please continue to Section 5

Section 5 - Your Coping Strategy

This section includes descriptions of 4 situations that you may have experienced or may experience in the future. Each situation is followed by 6 statements about thoughts, concerns and actions people may have in such a situation. Please try to imagine that you are in each situation and indicate for **each** statement to what degree it is applicable to you, by encircling your answer.

1 = Not at all applicable to me

2 = Not very applicable to me

3 = A little bit applicable to me

4 = Rather applicable to me

5 = Strongly applicable to me

Please give an answer for all six items within each scenario. There are no right or wrong answers.

Q. 22	Imagine you have been suffering from headaches and dizziness for some time. You visit your GP. The doctor tells you things don't look too good and refers you to a specialist for further medical examination and tests. Please select one for each row.					
		Not at all applicable to me 1	Not very applicable to me 2	A little bit applicable to me 4	Rather applicable to me 4	Strongly applicable to me 5
I plan to ask the specialist as many questions as possible		1	2	3	4	5
I think things will turn out to be alright		1	2	3	4	5
I decide to gather more information from the other doctors or medical centres before I see the specialist		1	2	3	4	5
I plan to start reading about headaches and dizziness		1	2	3	4	5
For the time being I try not to think of unpleasant outcomes		1	2	3	4	5
I am not going to worry. Such an examination and tests is not as bad as suffering from headaches all the time		1	2	3	4	5

Q. 23

Imagine you work hard and are overweight. Your GP has advised you that this is unhealthy several times before. During a GP visit the doctor tells you that you have hypertension (high blood pressure). Please select one for each row.

	Not at all applicable to me 1	Not very applicable to me 2	A little bit applicable to me 4	Rather applicable to me 4	Strongly applicable to me 5
I look at the blood pressure machine to ensure the doctor isn't mistaken	1	2	3	4	5
I take things easy	1	2	3	4	5
I decide to continue living normally	1	2	3	4	5
I ask the GP extensive questions about the risks and consequences of high blood pressure	1	2	3	4	5
I tell myself some medical conditions are worse than this	1	2	3	4	5
I plan to start reading a lot about hypertension	1	2	3	4	5

Q. 24

Imagine you have angina (chest pains) and your specialist advises a heart operation. The specialist informs you that (s)he is not certain how effective an operation will be. You will have to wait 4 months for the operation.

	Not at all applicable to me 1	Not very applicable to me 2	A little bit applicable to me 4	Rather applicable to me 4	Strongly applicable to me 5
I take the view that in my case the operation will be effective	1	2	3	4	5
I decide to find out all that is known about heart surgery	1	2	3	4	5
I decide to undertake as many pleasant and useful activities as possible in the next few months	1	2	3	4	5
I am going to find out whether there is a chance that the operation will make things worse	1	2	3	4	5
I decide to contact other patients with the same medical problem for information	1	2	3	4	5
I tell myself things will turn out to be alright	1	2	3	4	5

Q. 25	Imagine you have become very breathless. Your doctor has diagnosed the cause as 'chronic heart failure' and recommends that you have a cardiac resynchronization defibrillator device implanted. The specialist informs you that he is not certain how effective the device will be. Please select one for each row.				
	Not at all applicable to me 1	Not very applicable to me 2	A little bit applicable to me 4	Rather applicable to me 4	Strongly applicable to me 5
I tell the doctor that I want to know everything there is to know about the device	1	2	3	4	5
I surf the internet for as much information as possible	1	2	3	4	5
I ask myself whatever can go wrong	1	2	3	4	5
I decide to relax now in the face of what is coming to me	1	2	3	4	5
I tell myself things will turn out to be alright	1	2	3	4	5
I immediately contact somebody who has a device and may inform me a bit about the operation	1	2	3	4	5

The Threatening Medical Situations Inventory (TMSI) (van Zuuren et al., 1996, van Zuuren and Hanewald, 1993) - Adapted to include CRMD decision scenario with permission

Finally please continue to Section 6

Section 6 - Your Decision Making

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Please describe how you reached a decision regarding device implantation by ticking the boxes. You may include further information if you wish.

Please tick all the boxes that apply:

Q. 26	When you were recommended a cardiac device (ICD or CRT) did you seek further information from:			
	The consultant		Other patients with no device	
	Your GP		Hospital leaflet / information	
	The specialist nurse		GP leaflet / information	
	The cardiac physiologist / technician		TV or radio	
	Your spouse / partner		General websites	
	Other family members eg parents		Service user / patient websites	
	Friends		Professional websites eg NICE, BHF	
	Other patients with a device		I did not require any more information	
	Other (please specify):			

Q. 27	Who and / or what do you think was the most influential in helping you to reach your decision?

Your Decision

How much control **would you have liked** over the final decision?

Please rank the order in which the statements describe your preference for decision making regarding device therapy by indicating in the box below, from **1 (most preferred) to 5 (least preferred).** You should give a different number between 1 and 5 for each statement.

Q. 28	I prefer to:	
	Make the final selection about which treatment I will receive	
	Make the final selection of my treatment after seriously considering my doctor`s opinion	
	Have my doctor and I share responsibility for deciding what treatment is best for me	
	Have my doctor make the final decision about which treatment will be used, but seriously considers my opinion	
	Leave all decisions regarding my treatment to my doctor	

The Control Preference Scale (Degner et al., 1997b) - Adapted with permission

What decision have you reached?

Q. 29	To accept device implantation	
	To decline device implantation for the time being	
	To decline device implantation completely	
	Still undecided	
	Other; please explain	

Your Decision

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How much control **did you actually have** over the final decision?

Please tick the statement which most closely describes your actual involvement in making the final decision regarding device therapy.

Q. 30	I made the final decision about device implantation	
	I made the final decision about device implantation after seriously considering my doctor`s opinion	
	My doctor and I shared responsibility for deciding whether I should have device implantation	
	My doctor made the final decision about device implantation, but seriously considered my opinion	
	I left the final decision regarding device implantation to my doctor	

The Control Preference Scale (Degner et al., 1997b) - Adapted with permission

With respect to the decision you made regarding device therapy, please indicate on the 1 to 5 scale whether you agree or disagree with each of the following options:

Q. 31		Strongly Agree 1	Agree 2	Neither agree or disagree 4	Disagree 4	Strongly disagree 5
	It was the right decision	1	2	3	4	5
	I regret the choice that was made	1	2	3	4	5
	I would go for the same choice if I had to do it over again	1	2	3	4	5
	The choice did me a lot of harm	1	2	3	4	5
	The decision was a wise one	1	2	3	4	5

The Decision Regret Scale (Brehaut et al., 2003; O'Connor, 1996) - Adapted with permission

Thank you very much for taking the time to complete the questionnaire.

Please return your completed questionnaire to me in the stamped addressed envelope provided, but before you do I have one more favour to ask!

In order to gain more insight in to the answers you have given and gain a deeper understanding of how you reached your decision, I would like to invite you to participate in a single, audio recorded interview which will last approximately 1 hour. Any additional written notes taken during the interview will be shared with you prior to closure of the interview. The interview will be arranged to coincide with your next cardiology outpatient appointment, to take place in a meeting room at the hospital at a time convenient to you.

You are not under any obligation to agree to the interview now or later and you can return the questionnaire without completing the details below, but if you think you may be interested in participating or would like to discuss this further please indicate your permission for me to contact you below:

Please tick all the boxes that apply:

Morning 9am to 12.00 midday		By home phone which is:
Afternoon 12.00 midday to 6pm		By mobile which is:
Evening 6pm to 9pm		By email which is:
Weekend		Other (please specify):

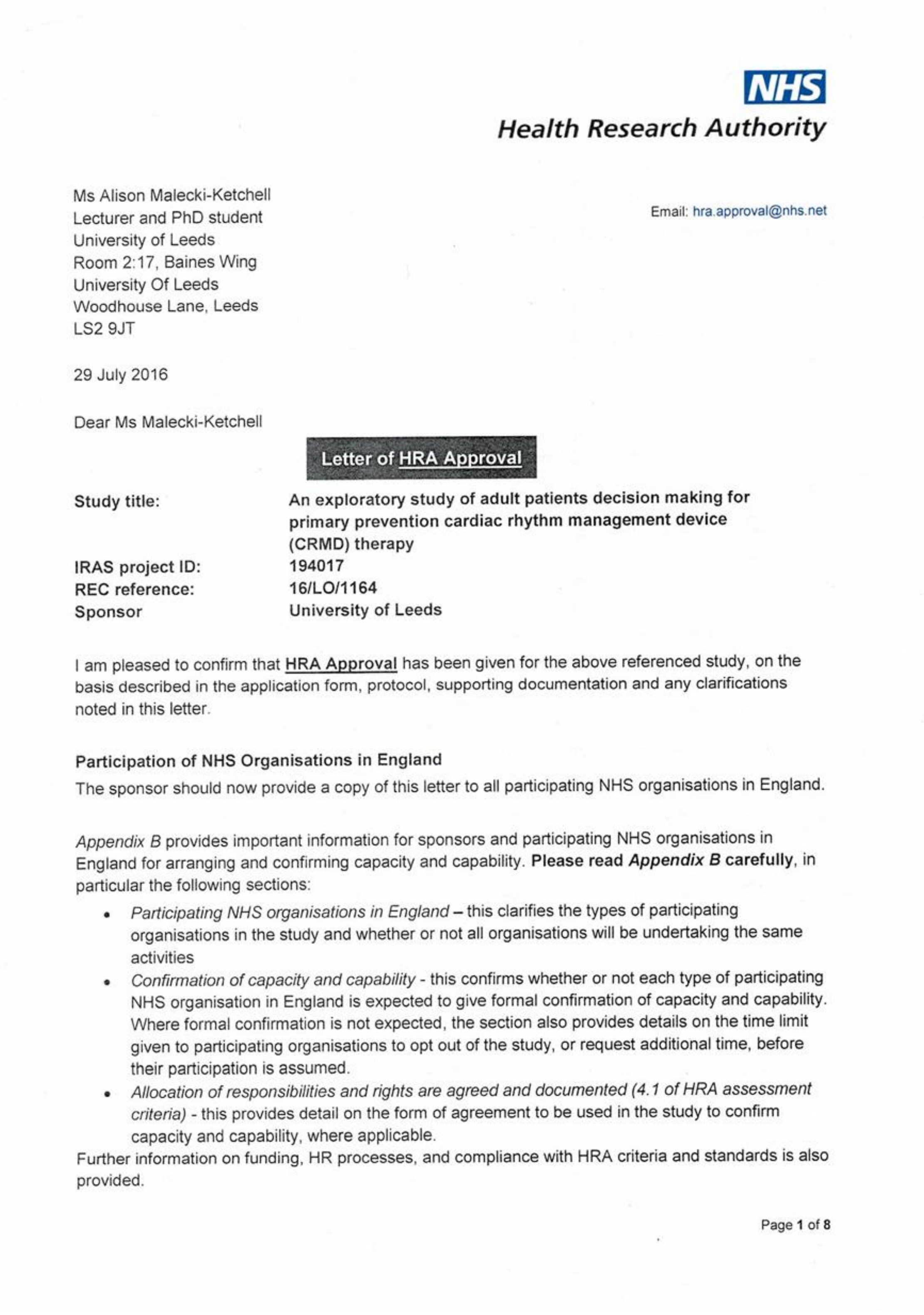
With your permission, I will contact you to discuss the study further before you agree to participate. Alternatively, if you are not selected to participate in the interview or you decide not to take part, gratitude for your involvement in part 1 and interest in part 2 will be acknowledged at the time and in writing.

If you wish to discuss any aspect of this study further please don't hesitate in contacting me on:
Landline – 0113 3431258 (voicemail available)
E mail – a.c.ketchell@leeds.ac.uk

I look forward to receiving you questionnaire
Thank you and best wishes

Alison Malecki-Ketchell

Appendix J Health Research Authority Approval



NHS
Health Research Authority

Ms Alison Malecki-Ketchell
Lecturer and PhD student
University of Leeds
Room 2:17, Baines Wing
University Of Leeds
Woodhouse Lane, Leeds
LS2 9JT

Email: hra.approval@nhs.net

29 July 2016

Dear Ms Malecki-Ketchell

Letter of HRA Approval

Study title:	**An exploratory study of adult patients decision making for primary prevention cardiac rhythm management device (CRMD) therapy**
IRAS project ID:	**194017**
REC reference:	**16/LO/1164**
Sponsor	**University of Leeds**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

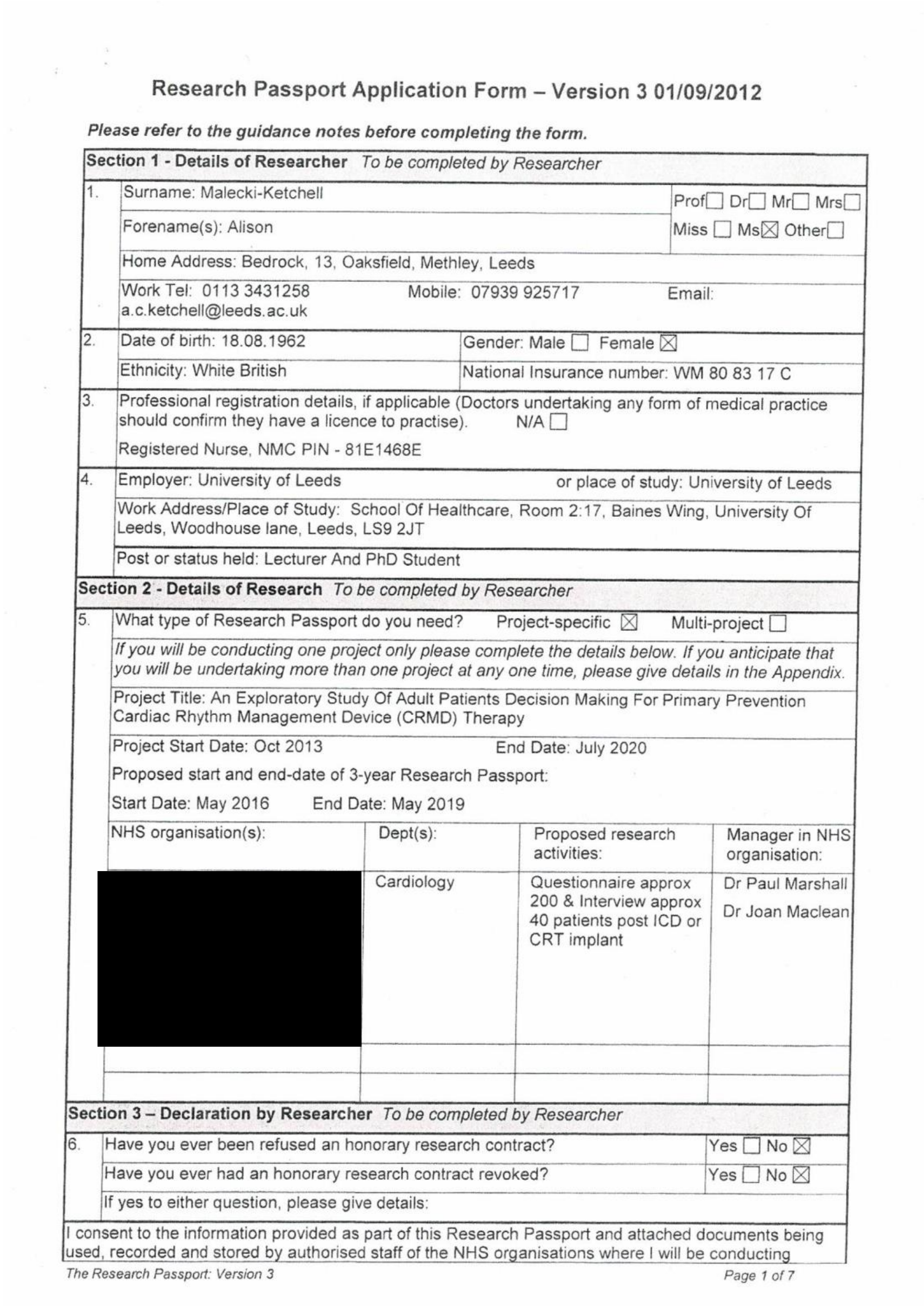
The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Appendix K Research And Development Multi-centre Study Passport



Research Passport Application Form – Version 3 01/09/2012

Please refer to the guidance notes before completing the form.

Section 1 - Details of Researcher *To be completed by Researcher*

1\. Surname: Malecki-Ketchell

Prof☐ Dr☐ Mr☐ Mrs☐ Miss ☐ Ms☒ Other☐

Forename(s): Alison

Home Address: Bedrock, 13, Oaksfield, Methley, Leeds

Work Tel: 0113 3431258 Mobile: 07939 925717 Email: a.c.ketchell@leeds.ac.uk

2\. Date of birth: 18.08.1962 Gender: Male ☐ Female ☒

Ethnicity: White British National Insurance number: WM 80 83 17 C

3\. Professional registration details, if applicable (Doctors undertaking any form of medical practice should confirm they have a licence to practise). N/A ☐

Registered Nurse, NMC PIN - 81E1468E

4\. Employer: University of Leeds or place of study: University of Leeds

Work Address/Place of Study: School Of Healthcare, Room 2:17, Baines Wing, University Of Leeds, Woodhouse lane, Leeds, LS9 2JT

Post or status held: Lecturer And PhD Student

Section 2 - Details of Research *To be completed by Researcher*

5\. What type of Research Passport do you need? Project-specific ☒ Multi-project ☐

If you will be conducting one project only please complete the details below. If you anticipate that you will be undertaking more than one project at any one time, please give details in the Appendix.

Project Title: An Exploratory Study Of Adult Patients Decision Making For Primary Prevention Cardiac Rhythm Management Device (CRMD) Therapy

Project Start Date: Oct 2013 End Date: July 2020

Proposed start and end-date of 3-year Research Passport:

Start Date: May 2016 End Date: May 2019

NHS organisation(s):	Dept(s):	Proposed research activities:	Manager in NHS organisation:
[redacted]	Cardiology	Questionnaire approx 200 & Interview approx 40 patients post ICD or CRT implant	Dr Paul Marshall Dr Joan Maclean

Section 3 – Declaration by Researcher *To be completed by Researcher*

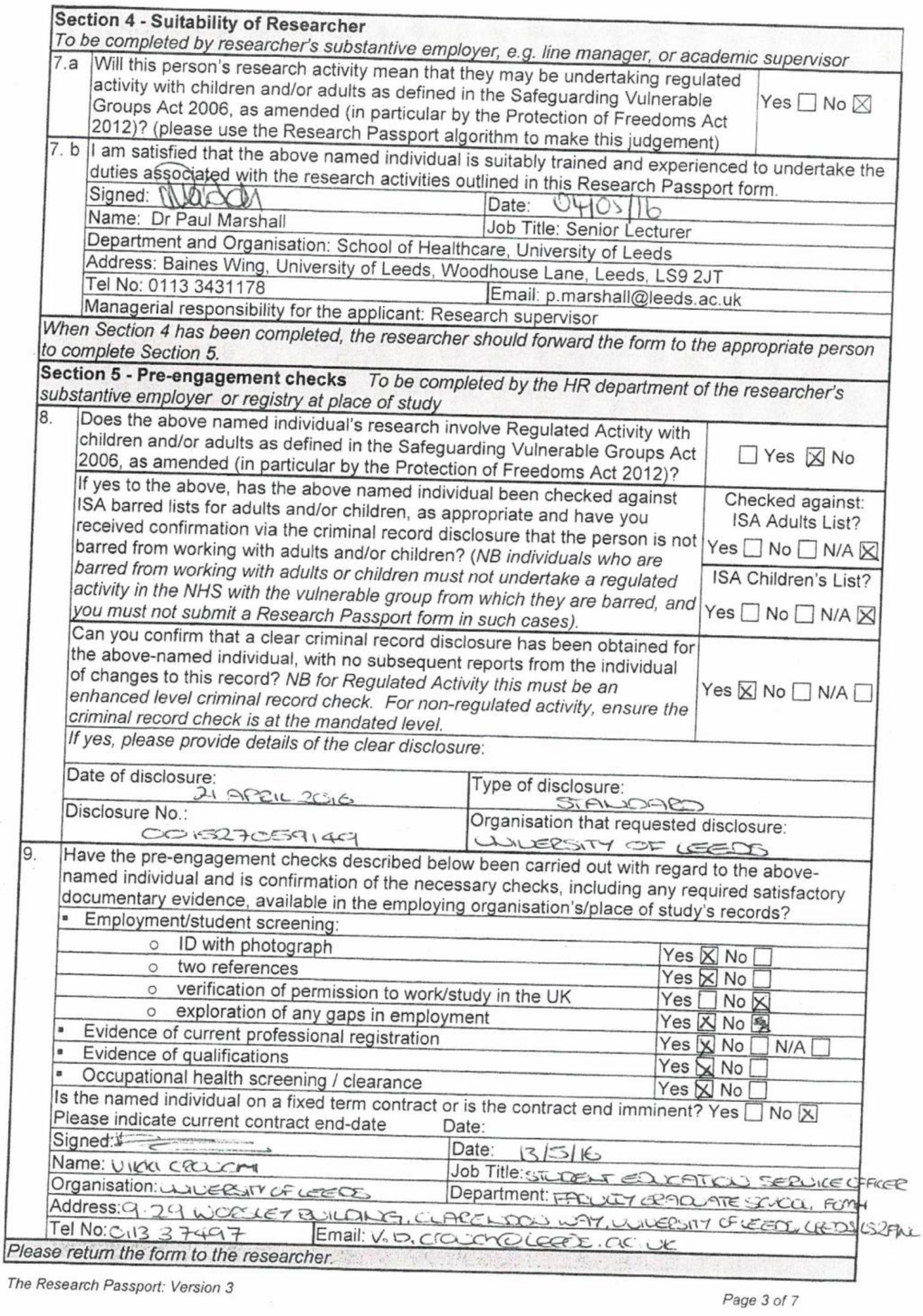
6\. Have you ever been refused an honorary research contract? Yes ☐ No ☒

Have you ever had an honorary research contract revoked? Yes ☐ No ☒

If yes to either question, please give details:

I consent to the information provided as part of this Research Passport and attached documents being used, recorded and stored by authorised staff of the NHS organisations where I will be conducting

The Research Passport: Version 3 *Page 1 of 7*



Section 4 - Suitability of Researcher

To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor

7.a	Will this person's research activity mean that they may be undertaking regulated activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)? (please use the Research Passport algorithm to make this judgement)	Yes ☐ No ☒

7. b I am satisfied that the above named individual is suitably trained and experienced to undertake the duties associated with the research activities outlined in this Research Passport form.

Signed:
Date: 04/05/16
Name: Dr Paul Marshall
Job Title: Senior Lecturer
Department and Organisation: School of Healthcare, University of Leeds
Address: Baines Wing, University of Leeds, Woodhouse Lane, Leeds, LS9 2JT
Tel No: 0113 3431178
Email: p.marshall@leeds.ac.uk
Managerial responsibility for the applicant: Research supervisor

When Section 4 has been completed, the researcher should forward the form to the appropriate person to complete Section 5.

Section 5 - Pre-engagement checks *To be completed by the HR department of the researcher's substantive employer or registry at place of study*

8.	Does the above named individual's research involve Regulated Activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)?	☐ Yes ☒ No
	If yes to the above, has the above named individual been checked against ISA barred lists for adults and/or children, as appropriate and have you received confirmation via the criminal record disclosure that the person is not barred from working with adults and/or children? (*NB individuals who are barred from working with adults or children must not undertake a regulated activity in the NHS with the vulnerable group from which they are barred, and you must not submit a Research Passport form in such cases).*	Checked against: ISA Adults List? Yes ☐ No ☐ N/A ☒ ISA Children's List? Yes ☐ No ☐ N/A ☒
	Can you confirm that a clear criminal record disclosure has been obtained for the above-named individual, with no subsequent reports from the individual of changes to this record? *NB for Regulated Activity this must be an enhanced level criminal record check. For non-regulated activity, ensure the criminal record check is at the mandated level.*	Yes ☒ No ☐ N/A ☐

If yes, please provide details of the clear disclosure:

Date of disclosure: 21 APRIL 2016
Type of disclosure: STANDARD
Disclosure No.: 001527059149
Organisation that requested disclosure: UNIVERSITY OF LEEDS

9\. Have the pre-engagement checks described below been carried out with regard to the above-named individual and is confirmation of the necessary checks, including any required satisfactory documentary evidence, available in the employing organisation's/place of study's records?

▪ Employment/student screening:	
○ ID with photograph	Yes ☒ No ☐
○ two references	Yes ☒ No ☐
○ verification of permission to work/study in the UK	Yes ☐ No ☒
○ exploration of any gaps in employment	Yes ☒ No ☒
▪ Evidence of current professional registration	Yes ☒ No ☐ N/A ☐
▪ Evidence of qualifications	Yes ☒ No ☐
▪ Occupational health screening / clearance	Yes ☒ No ☐

Is the named individual on a fixed term contract or is the contract end imminent? Yes ☐ No ☒
Please indicate current contract end-date Date:

Signed:
Date: 13/5/16
Name: VIKKI CROUCH
Job Title: STUDENT EDUCATION SERVICE OFFICER
Organisation: UNIVERSITY OF LEEDS
Department: FACULTY GRADUATE SCHOOL, FOMH
Address: 9.29 WORSLEY BUILDING, CLARENDON WAY, UNIVERSITY OF LEEDS, LEEDS LS2 9NL
Tel No: 0113 37497
Email: V.D.CROUCH@LEEDS.AC.UK

Please return the form to the researcher.

The Research Passport: Version 3

Page 3 of 7

Appendix L HRA Study Amendment Approval

From: AMENDMENTASSESSMENT, Hra (HEALTH RESEARCH AUTHORITY) [mailto:hra.amendmentassessment@nhs.net]
Sent: 05 February 2018 10:29
To: Alison Malecki-Ketchell <A.C.Ketchell@leeds.ac.uk>; Medicine and Health Research Governance <governance-ethics@leeds.ac.uk>
Cc: lthtresearch (LEEDS TEACHING HOSPITALS NHS TRUST) <leedsth-tr.lthtresearch@nhs.net>; AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>
Subject: RE: IRAS 194017. SA01 HRA Assessment of Amendment Complete

Dear Ms Malecki-Ketchell,

Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Kevin Ahmed

Assessor

Health Research Authority

Room 001 | Jarrow Business Centre | Rolling Mill Rd, Jarrow | NE32 3DT

T. 0207 104 8171

E. Kevin.Ahmed1@nhs.net

W. www.hra.nhs.uk

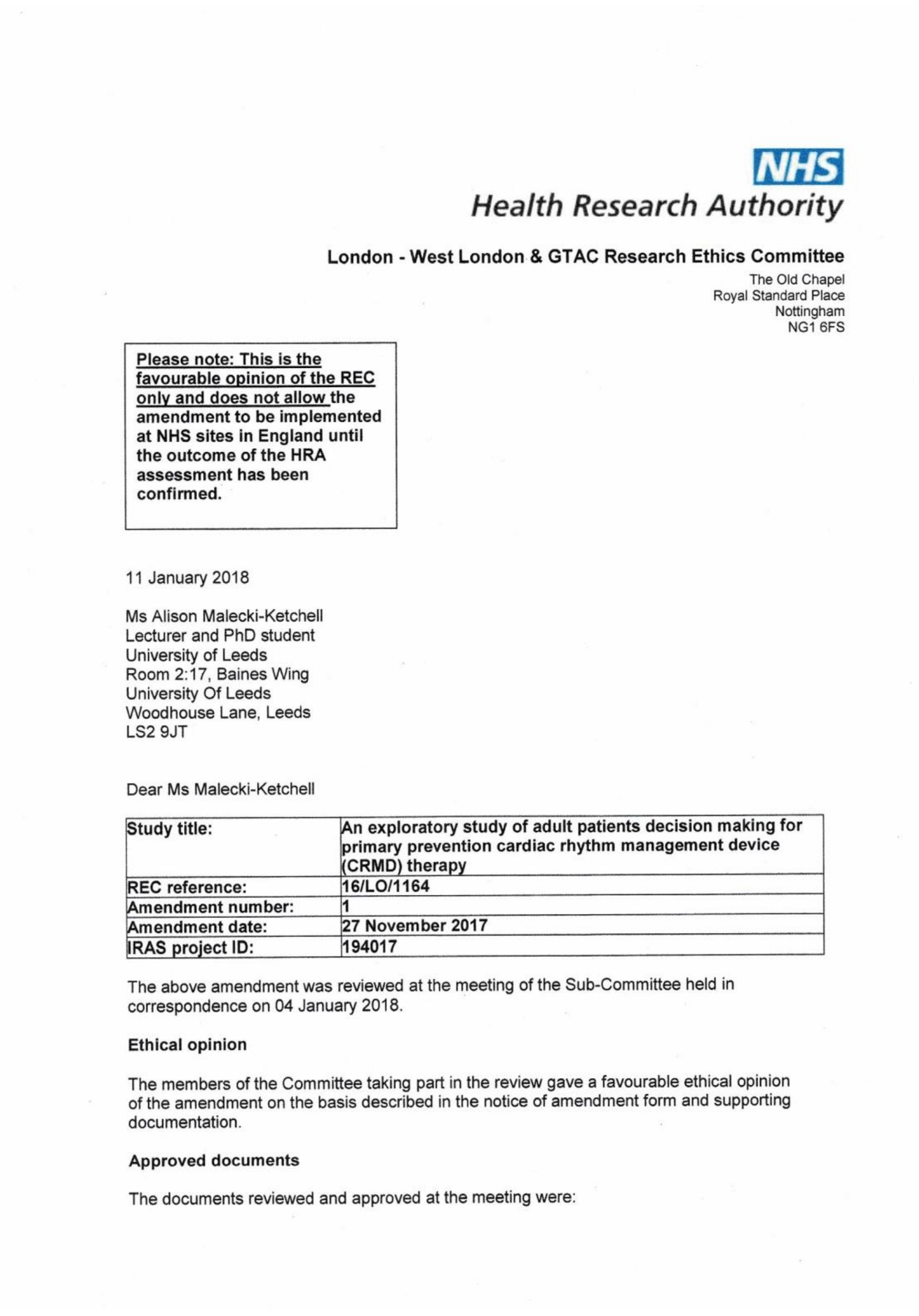
Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Ms Malecki-Ketchell,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.



NHS
Health Research Authority

London - West London & GTAC Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

11 January 2018

Ms Alison Malecki-Ketchell
Lecturer and PhD student
University of Leeds
Room 2:17, Baines Wing
University Of Leeds
Woodhouse Lane, Leeds
LS2 9JT

Dear Ms Malecki-Ketchell

Study title:	**An exploratory study of adult patients decision making for primary prevention cardiac rhythm management device (CRMD) therapy**
REC reference:	**16/LO/1164**
Amendment number:	**1**
Amendment date:	**27 November 2017**
IRAS project ID:	**194017**

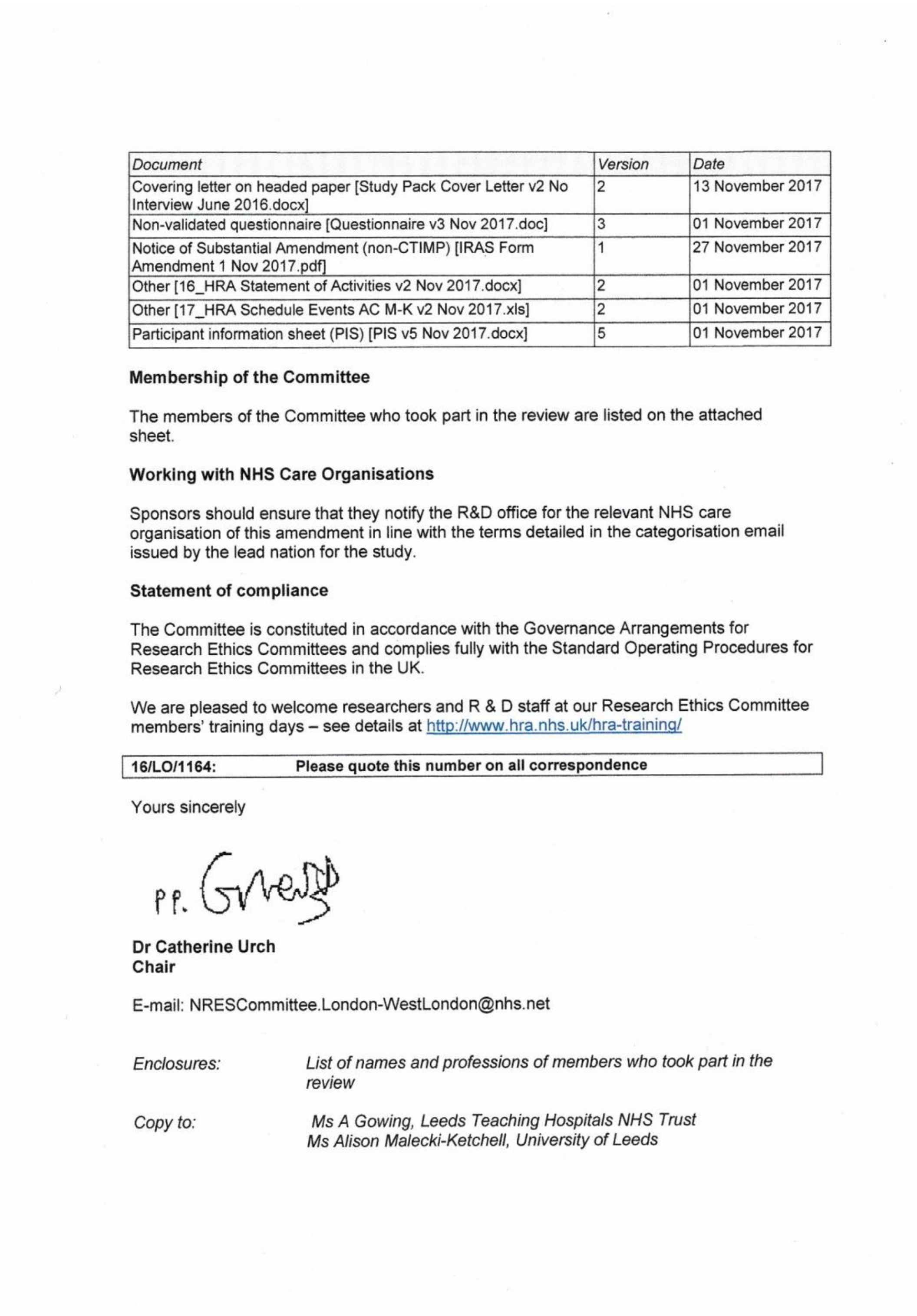
The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence on 04 January 2018.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:



Document	*Version*	*Date*
Covering letter on headed paper [Study Pack Cover Letter v2 No Interview June 2016.docx]	2	13 November 2017
Non-validated questionnaire [Questionnaire v3 Nov 2017.doc]	3	01 November 2017
Notice of Substantial Amendment (non-CTIMP) [IRAS Form Amendment 1 Nov 2017.pdf]	1	27 November 2017
Other [16_HRA Statement of Activities v2 Nov 2017.docx]	2	01 November 2017
Other [17_HRA Schedule Events AC M-K v2 Nov 2017.xls]	2	01 November 2017
Participant information sheet (PIS) [PIS v5 Nov 2017.docx]	5	01 November 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1164:	**Please quote this number on all correspondence**

Yours sincerely

PP.

Dr Catherine Urch
Chair

E-mail: NRESCommittee.London-WestLondon@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Ms A Gowing, Leeds Teaching Hospitals NHS Trust* *Ms Alison Malecki-Ketchell, University of Leeds*

Appendix M Strand 2 Interview Schedule

UNIVERSITY OF LEEDS
School of Healthcare

Interview Schedule And Prompts

Thank you for agreeing to take part in this interview. The purpose of the interview is to allow me to gain more insight and understanding of the way in which you reached your decision regarding cardiac device implantation. The interview is expected to take approximately one hour and you are free to stop participating at any time. All information obtained from you will remain strictly confidential.

Are you happy for me to record the interview?

Do you have any further questions regarding the interview before we start?

Collect questionnaire if necessary

Opener –

1. Tell me how you came to be offered an ICD / CRT?
   (*To glean patient understanding & experience of underlying cardiac condition, severity of illness, symptoms and perception of risk and role of ICD*)

2. What happened then?
   (*To glean a sense of the patient journey, who, where, when, from whom, how did they receive information*)

3. At what point / when did you arrive at your decision to accept / decline ICD?

4. Tell me about how you made the decision?

5. Can you describe your thoughts – how did you feel? what you thought & did during your decision making?
   (*To explore individual processes and reveal any potential systematic and heuristic tendencies*)

6. Can you describe your actions ie who, what, where, when, why, how, what you thought & did during your decision making?
   (*To explore collective processes and reveal any potential systematic and heuristic tendencies*)

7. What, where, when and from whom did you gather information?

8. Did you feel that you had enough information and understanding to inform your decision? (*To explore information exchange and recall*)

9. Did you feel that the doctor / nurse attempted to establish what your thoughts, feelings and opinions were?

10. If so, how did they do that?

11. Who and / or what factors do you think influenced the way you reached your decision? (*Glean from demographics, coping styles & interviews. Consider values, beliefs and preferences*)

12. Who and / or what would you say influenced your decision to accept / refuse CRMD? (*To establish influencing factors especially values, beliefs, preferences*)

13. What if any factors were most / least important to you? What were the deciding / key factors in your decision to accept / decline

14. Who would you say took responsibility for the ultimate decision?

15. Did you feel that you had the desired level of control over your decision that you wanted? (*Decisional control preferences scale*)

16. How did you / that make you feel?

17. What would have made a difference to your decision making?

18. What would have helped you in making your decision?

19. How do you feel now that you have the device implanted / without the device?

20. Is there anything further related to your decision making that we haven't discussed that you would like to share with me?

Thank you for taking the time to take part in this interview

Appendix N Example Of Interview Transcript Coding

L2	84	No, I didn't see *ICD Nurse* till after I'd left hospital and after they took me off urm …they took me off the warfarin …	6.2
L2	85	and basically I was told .. not in an abrupt way … but very down to earth way, well take if you get one fitted it'll prevent imminent death in the event of a heart attack … so…	6.5; 7.5; 9.2; 15.1; 18.6; 20.6
L2	86	that kind of made my mind up for me.	2.2a; 2.3; 7.5; 15.1; 20.6
L2	87	However it want urm it want nasty or wrong it was ..	18.6; 20.6
L2	88	if anything it suited how I am OK	18.6; 20.6
L2	89	straight facts and then that's it you can make a decision based on that yeah	2.2a; 2.3; 7.5; 18.6; 20.6
L2	90	AMK	
L2	91	So at that point did you have any knowledge about what devices do?	2.2b; 8.2a
L2	92	L2	
L2	93	No, all I knew was it basically I've seen on tel, on films and television where	2.2b; 8.2a
L2	94	they pump people (demonstrates holding defib paddles and shock) and they press them well its same as that but it's inside your chest.	2.2b; 9.2; 9.3
L2	95	And I said fine well like I say you're better to have something ..	2.3; 3.8; 7.5; 8.2a; 14.3; 19.4; 19.17
L2	96	er it was explained to me by Doctor *Consultant*, it's preventative medicine ahha really.	6.5; 7.5; 9.1; 18.6; 19.10
L2	97	That's why I wanted it fitted as it's acting as preventative medicine yeah which made it a bit more clearer to me	6.5; 7.5; 9.1; 18.6; 19.10
L2	98	*AMK should have, but didn't ask about thoughts, feelings, opinions etc about possibility of receiving shock therapy at this point*	
L2	99	AMK	
L2	100	Yes that's absolutely right. So would you say that you formulated your decision to have it there and then?	2.3
L2	101	L2	
L2	102	Yeeeess ….Yes because everything I got told it was matter of fact if you don't have it your wasting your time and …	2.2a; 2.3; 3.8; 7.5; 14.3; 18.6; 20.5; 20.6
L2	103	it was good to be told that way because then you know ….	2.2a; 2.3; 3.8; 7.5; 14.3; 18.6; 20.5; 20.6
L2	103	He put it to me straight how I like things to be put to me and urm …	2.2a; 2.3; 3.8; 7.5; 14.3; 18.6; 20.5; 20.6
L2	105	I can't see why anybody … it's like someone saying .. it's like a woman being pregnant do you want an epidural … no I'll sit there and suffer …	2.7; 2.10a; 7.5; 19.6; 25
L2	106	well why would anyone want to do that yeah unless you want to be a martyr.	2.7; 2.10a; 7.5; 19.6; 25
L2	107	To me that doesn't make sense and er, by having something, you've got something that in the event it was to work … good.	2.7; 14.3; 14.8; 19.4; 19.6; 19.10; 19.17
L2	108	In the event it wasn't to work ….. tough s**t	14.3; 14.8; 19.4; 19.6; 19.17
L2	109	but at least you've got it if it was to work yeah so leave it at that kind of situation.	14.3; 14.8; 19.4; 19.6; 19.17
L2	110	AMK	
L2	111	So it's for that prevention or like a safety net?	
L2	112	L2	
L2	113	Yeah you've a greater chance with it if you have it fitted than without it …	15.1; 19.4; 19.6; 19.10; 19.17
L2	114	and for what it is why don't you just have it done	7.5; 15.1; 19.4; 19.6; 19.10; 19.17