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Malecki-Ketchell, A, Marshall, P orcid.org/0000-0002-2505-4377 and Maclean, J (2017) Adult Patient Decision-making Regarding Implantation Of Complex Cardiac Devices: A Scoping Review. *European Journal of Cardiovascular Nursing*, 16 (7). pp. 567-584. ISSN 1474-5151

<https://doi.org/10.1177/1474515117715730>

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Adult Patient Decision-making Regarding Implantation Of Complex Cardiac Devices: A Scoping Review

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Abstract

Background:

Complex cardiac rhythm management device (CRMD) therapy provides an important treatment option for people at risk of sudden cardiac death (SCD). Despite the survival benefit, device implantation is associated with significant physical and psychosocial concerns presenting considerable challenges for the decision-making process surrounding CRMD implantation for patients and physicians.

Aims:

The purpose of this scoping review was to explore what is known about how adult (>16 years) patients make decisions regarding implantation of CRMD therapy.

Methods:

Published, peer-reviewed, English-language studies from 2000 to 2016 were identified in a search across eight healthcare databases. Eligible studies were concerned with patient decision-making for first time device implantation. Quality assessment was completed using the Mixed Methods Appraisal Tool (MMAT) for all studies meeting the inclusion criteria.

Results:

The findings of 8 qualitative and 7 quantitative studies, including patients who accepted or declined primary or secondary SCD prevention devices, were clustered in to two themes; knowledge acquisition and the process of decision-making, exposing similarities and distinctions with the treatment decision-making literature.

Conclusion:

The review revealed some insight in to the way patients approach decision-making but also exposed a lack of clarity and research activity specific to CRMD patients. Further research is

recommended to support the development and application of targeted decision support mechanisms.

Key Words:

Scoping review; implantable cardioverter defibrillator (ICD); cardiac resynchronisation therapy (CRT); cardiac device implantation; patient decision-making.

Introduction

Sudden cardiac death (SCD) is a global problem. The exact incidence of SCD in Europe and the US remains unclear though it is responsible for an estimated 15 to 20% of all deaths¹. It is usually the result of ventricular arrhythmia, most often associated with underlying heart disease or inherited conditions². Meta-analysis of large randomised controlled trials has firmly established the survival benefit of complex cardiac rhythm management devices (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 sudden cardiac arrest (SCA)³⁻⁶. Despite the evident survival benefit, CRMD implantation is associated with significant potential complications and substantial patient and partner physical and psychosocial concerns⁷. The enormity and uncertainty of both benefits and harms present challenges for the decision-making process surrounding CRMD implantation for patients and healthcare professionals. 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 device⁷.

A wealth of existing knowledge related to patient treatment decision-making; in the context of life threatening conditions and the presence of uncertainty, complexity and limited rationality; refers predominantly to cancer with less emphasis upon cardiovascular disease. The literature describes the distinction and interplay between individual and collective, participatory aspects of treatment decision-making⁸. Individual decision-making refers to systematic and non-systematic (heuristic) methods of gathering information⁹⁻¹². 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 others¹³⁻¹⁵. Shared decision-making (SDM) is widely advocated as the gold standard in the literature¹⁵⁻¹⁸, yet while most patients appear to prefer a joint approach¹⁹, a significant minority favour a passive style and others a more active approach²⁰⁻²⁴. Factors such as patient demographics, condition, severity and healthcare experience appear to influence preference for involvement²⁰⁻³⁰. A connection between achieving the desired level of involvement, being informed and decisional satisfaction has been reported^{22, 31-34}, yet discordance between desired and actual decisional control appears to be prevalent^{21, 24, 32, 35-38}. Regardless of level of participation, widespread misunderstanding and dissatisfaction with the amount of information received appears to be common^{22, 23, 26, 39, 40}. Given the context of serious, sudden life threatening cardiac arrhythmia and the uniqueness of device therapy it is not known whether findings from the broader literature can be applied to patients making

decisions regarding CRMD implantation. In view of this, a scoping review was undertaken to discover 'what is known about how adult (>16 years) patients make decisions regarding implantation of complex cardiac rhythm management device (CRMD) therapy'.

Method

A five stage scoping framework⁴¹ was used to explore the extent, range and nature of available knowledge, identify gaps in the existing literature, establish key areas for further study and consider implications for practice. The scoping framework involved developing the research question, identifying relevant studies, study selection, charting the data and reporting the results. The framework was further refined to include an analysis of quality⁴²⁻⁴⁵.

The eligibility criteria (Table 1) were deliberately broad and not restricted by study design. Exclusion parameters were developed iteratively in response to exposure to the literature, to ensure that patient decision-making related to CRMD remained the focal point of the review. The search strategy was designed to locate good quality, relevant studies published in English from the year 2000, reflecting the fact that complex CRMD was not in mainstream practice until the 1990's. Search terms such as: adult patient and cardiac arrest or disease or failure or myopathy, and implantable defibrillator or device therapy and decision making; and subject headings were applied across eight databases (Table 2) particular to medicine, psychology, nursing, allied health publications and four grey literature databases. Hand searching of cardiology and decision-making journals and citation tracking ensured inclusivity. Titles and abstracts were searched (AM-K) for relevance against eligibility criteria retaining 244 (Table 1). Following removal of duplications, 173 citations were organised into include (n=35), unsure (n=8) and exclude (n=130) groups and full text scrutinised. Alternative publications of the same dataset were pooled and papers which did not meet the inclusion criteria or provide sufficient detail for analysis were excluded resulting in 15 studies. Independent review (PM) of a random sample of 30 citations confirmed eligibility (Figure 1). The Mixed Methods Appraisal Tool (MMAT)⁴⁶ was used to appraise methodological quality. This tool allows assessment of quantitative, qualitative and mixed methods designs; has good reported validity and reliability⁴⁶⁻⁴⁸ and has been used in previous reviews^{49, 50}. Research design, method and key findings extracted from the primary studies were collated into a detailed data chart to enable identification, interpretation and synthesis of commonalities, themes and gaps in the literature^{41,45}.

Results

Overview of methodological approaches

Of the 3451 citations retrieved, 15 studies fulfilled the inclusion criteria. Table 3 presents a condensed numerical analysis of the extent, nature and distribution of the research. 8 qualitative studies, 6 non randomised cohort trials and 1 integrative review were published between 2007 and 2016. All studies were conducted in North America (US or Canada) with the exception of Agard⁵¹ (Sweden), Groarke⁵² (Ireland) and Chan⁵³ (Singapore). Sample sizes ranged from 8⁵⁴ to 240⁵³ patients post CRMD recommendation. Several studies recruited from local or national registers or more than one implant centre^{52, 55-59}. A ratio of 2-4 men to 1 woman were represented with the exception of 1:1 in Hauptman⁵⁶. Mean age

ranged from 54.86 to 69 years with the exception of Lucas⁵⁴ who targeted older adults (mean 84 years). Six studies^{53, 55, 57, 60-62} included mixed race participants though the majority were Caucasian and other demographic information such as marital status, educational level was scarcely reported. One study focused upon secondary ICD⁵¹, six on primary ICD^{53, 57-59, 61, 62} and five^{52, 54, 56, 60, 63} included both ICD indications. Five studies included ICD and CRT^{52, 54, 56, 63, 64} and it was not clear which indication or device type Gal⁵⁵ referred to. Four studies^{58, 59, 61, 62} compared patients who accepted and declined devices, six^{51, 52, 54, 55, 60, 63} studied acceptors only and two^{53, 64} focused upon those who refused CRMD. With the exception of Hickman^{60, 65} 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. Data collection occurred between one and sixteen years post implant. 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. The integrative review⁴⁹ was concerned with the trajectory of decision-making from implant to the end of life. The review of initial implant decision featured eight^{51, 52, 56, 58, 59, 61, 63, 66} of the studies included in this analysis. Despite the distinction in focus, similarities in findings with this review emphasise commonalities in thematic interpretation. Overall, the level of reporting was variable but sufficient to enable quality assessment for all except one conference abstract⁶² providing limited methods information and the integrative review⁴⁹ which included an independent, comparative MMAT assessment. Of thirteen appraised studies, six scored 100%, four scored 75% and three 50% (Table 3).

Qualitative thematic analysis

The selected papers were organised into 'clusters' based upon study aims and within each cluster 'sub themes' emerged from the study findings (Table 4).

Cluster 1 : Device knowledge acquisition and recall

Sub Theme 1.1 Insight into condition, device role and function

Some recipients conveyed a lack of insight about their condition⁶²; the reason for implant^{52, 56}; and misunderstood device role and function often with inaccurate and over optimistic expectations of device therapy regardless of decision approach^{51-54, 56, 58, 61, 62, 64}. A poor understanding of role and function was associated with dissatisfaction with the lack of information⁵⁴.

Sub Theme 1.2 Physician communication and information received

There appeared to be a focus upon the 'benefit bias' presented in published guidelines. Some recipients reported a tendency for physicians to focus on the medical procedure, with knowledge of risk only becoming apparent when experienced post implant^{51, 56, 61}. 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^{51, 56}. Some recipients reported receiving advice about potential peri-procedural risks eg infection, bleeding but denied discussion of post implant complications such as lead displacement, ICD recall or inappropriate shock^{51, 52, 54, 56, 61}. Patients reported infrequent

reference to possible psychosocial outcomes eg anxiety, depression or QOL issues other than social concerns such as security devices⁵⁶. An emphasis upon ICD as the only option with minimal recall of any discussion of alternatives eg drug or ablation therapy existed^{51, 58}.

The use of decision aids did not feature in the ICD studies with the exception of Hazleton who designed and tested the ICD Decision Analysis Scale (ICD – DAS) and recommended its use in practice to facilitate information exchange and deeper discussion of patients knowledge, understanding and preferences for an ICD⁵⁷.

Cluster 2: The process of decision making

Sub Theme 2.1 Approaches to decision-making

The literature identified a combination of approaches reflecting the interplay between individual and collective decision making. 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^{51-56, 58, 61, 63}. Chan⁵³ reported that 235 (98%) relied solely upon expert opinion for information, whereas two studies^{52, 63} revealed an almost 50:50 split between passive and active decision makers. Participants 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 of and develop trust in the device to reach a decision^{52, 55, 58, 63, 64}.

Rather than distinct approaches, Carroll⁵⁸ described participants as occupying a position along a continuum between 'passive, indifferent' and 'active, engaged' decision-making. For some patients information transfer appeared to be the crucial element of, and synonymous with, involvement in decision-making rather than implementation of the final decision⁵⁸. Others made 'independent decisions' based upon their preferences whilst acknowledging guidance by physician recommendation or the experience of others as a potential influence^{58, 61, 64}.

Sub Theme 2.2 Factors influencing the decision style

Fluctuation in the level of engagement in decision-making appeared to be influenced by:

Age: older adults contemplating device therapy were more inclined to passivity deferring the decision to physician or family members^{54, 56} (small sample sizes limit generalisability).

Gender: despite little mention of potential gender differences, one study found that women were 2.7 times more likely than men to actively confirm their ICD decision to others and consider the physician to be a detailed information giver rather than authority figure^{55, 66}.

- Passivity was influenced by the degree of importance assigned to various situational factors:
- Perceived difficulty of the decision, fear and uncertainty^{51, 52, 54-56, 58, 61, 63}
- Symptom severity and current health state^{51, 54, 55, 58, 59, 61, 63}

- Insufficient perception of severity, symptomatology and minimised belief in personal risk and device necessity among some patients contemplating primary devices^{58, 59}. (Appreciation of personal risk prompted active involvement for others⁵⁸).
- Confidence and trust in physician recommendation^{51, 52, 54, 55, 58, 63}
- Lack of trust in the physician prompted passive reliance upon well informed family to support or make the decision^{55, 58, 59}.
- Social and family influence^{55, 58, 63}
- Insufficient time to deliberate^{51, 53, 55, 56, 58, 63}
- Pervading sense of 'no choice' and an 'offer you can't refuse', among some secondary ICD recipients who described themselves as laymen unable to have an opinion on such complex medical decisions^{51, 54, 55}.

Groarke⁵² explored desired and actual participation and found that 40 (53%) patients desired passive involvement with 35 (47%) reporting that the decision had been made by the physician. 35 (47%) preferred an active role but only 19 (25%) reported making independent choices⁵². Despite an apparent mismatch between desired and actual involvement, 70 (93%) respondents were satisfied with their decision⁵².

Sub Theme 2.3 Accepting or refusing device therapy

Acceptance was influenced by^{51, 52, 54, 55, 57-59, 61, 63}:

- Strength of, trust in and desire to heed physician recommendation
- Current health status and desire for life prolongation
- 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
- Family concerns

In contrast, patients more likely to decline CRMD^{53, 58, 59, 61, 62, 64}:

- Perceived the strength of recommendation to be weak
- Considered current health state to be satisfactory. (Particularly evident among primary prevention candidates who denied the personal risk of SCD and deemed the ICD unnecessary)
- Reported inadequate knowledge
- Valued quality of life over quantity
- Believed the burden of the device outweighed the benefit
- Belief that it would impose unwanted restrictions upon lifestyle
- The cost
- Invasive nature of the treatment
- Fear of complications
- Advancing age

Discussion

The widespread lack of knowledge and understanding of condition, device role, risks and alternative options across the CRMD studies is a concern. Reported inaccuracies 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 al⁵⁸

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^{56, 67}.

The ICD studies reviewed referred predominantly to patient – physician information exchange whereas many implant centres now adopt a multi professional approach. The focus upon benefit bias and procedural issues, rather than psycho-social outcomes resembles other studies which reveal differences in physician priority on survival and longevity over patients preference for preservation of quality of life⁶⁸. 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 physicians⁶⁹. This was reflected in a recent systematic review that concluded that most patients, regardless of intervention type overestimated benefit and underestimated harm⁷⁰. Thus there is a need for comprehensible, predictive information regarding benefits and risks to augment realistic expectations and informed choices^{70, 71}. 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 impact⁶⁹. In contrast, non physicians reported a greater emphasis upon psycho-social and quality of life concerns⁶⁹. 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 this⁷².

The decision approach may influence information exchange. Whilst SDM and collaborative styles are key topics in the decision-making literature⁷³⁻⁸⁰, the level of SDM in cardiology consultations is not well known⁸¹ and only one CRMD study alluded to patient perception of joint decision-making⁵². In contrast to the preference for SDM in the general literature^{24, 38, 76} reference to distinct passive and active approaches, dominated the CRMD studies. The majority of ICD patients desired passive involvement echoing findings among general cardiology patients³⁶. 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 informed choice^{14, 82, 83}, this approach could be appropriate in the context of post SCA secondary prevention where the benefit risk ratio is well established⁴. 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^{20, 84-88}.

However, passivity was also described among patients contemplating primary prophylactic devices^{53, 58, 61, 63} 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^{3, 5, 6}. Therefore reference to clinical guidelines for CRMD implantation, particularly when framed as essential rather than optional^{55, 59} 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. Furthermore, predictive risk stratification of inherited cardiac conditions is less established and the balance between not treating and risking a preventable arrhythmic event and the inevitable cost and complications associated with implantation is uncertain⁸⁹. 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^{55, 58, 59} or refusal of therapy⁵⁸. Ultimately, an explicit link between passivity, poorer knowledge and understanding described by the CRMD studies is problematic^{51, 53, 54, 58}.

In contrast, independent information gathering and leaving the ultimate treatment decision exclusively to CRMD patients presupposes that they are truly autonomous, that their information needs, values and preferences are known and they are certain of their wishes¹⁴. 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'^{39, 90, 91} and may explain the lack of accurate knowledge also found among 'active information seeking' device recipients⁶⁴. 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'^{9, 11}; thought to motivate some patients to accept or decline therapies^{15, 86}; was acknowledged among CRMD patients^{53, 61, 64}. 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 rational decision-making has been demonstrated^{9, 19, 37, 92-94}. Individuals could be induced to make sub-optimal decisions based upon positive or negative events that contradict physician advice⁵³. 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 degree to which primary and secondary 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^{13, 95-98}. The desire for information

exchange and deliberation expressed by some CRMD patients, whilst relinquishing responsibility for the final decision to physician expertise⁵⁸ was an indicator of active involvement in collaborative decision-making and may paradoxically represent a degree of autonomy^{22, 97, 99, 100}. 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^{74, 101-103}.

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^{16, 104-107}. However, thus far they have not been fully implemented in general practice^{103, 108} or in the context of CRMD uptake. The only CRMD study to develop and test a decision aid specific to ICD⁵⁷ 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 underway¹⁰⁹.

Although decision approach did not appear to influence device acceptance⁵⁸, inadequate knowledge was associated with device refusal^{53, 62} and dissatisfaction⁵⁴. 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-making⁸⁶. An association between increasing age, passivity and poor knowledge acquisition described in the general decision literature^{27, 29} was apparent among older adults contemplating device therapy^{54, 56}, 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^{39, 110-115} 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^{55, 66} though the tendency for women towards active engagement compares with other findings^{20, 23, 27, 97}. Consistent with the treatment literature⁸⁶ there is limited information regarding the influence of culture, ethnicity and other potential demographic differences in the CRMD studies. The impact of device indication, type and role as an indicator of health status, upon decision-making is uncertain due to the inclusion of primary and secondary devices in several studies, therefore a more focused investigative approach upon specific device types is recommended.

Limitations

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 underestimated. 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 potential loss of some important findings is therefore real.

Conclusion

This scoping review generated some insight in to the way patients approach decision-making related to CRMD recommendation, identified similarities and distinctions with the treatment decision-making literature and exposed a lack of clarity and research activity specific to some patients. It has demonstrated scope for an examination of relationships among a range of factors, with a particular focus upon device indication and use of valid outcome measures within a more judicious timeframe. Further insight in to what inspires active engagement, the degree and influence of heuristic thinking, time to deliberate and appropriateness of SDM for patients contemplating CRMD is recommended. Emphasis upon the development of strategies to enhance information assimilation and recall is essential. 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 and concordance, conflict, satisfaction and regret are scarce in the literature and warrant greater inclusion. 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 and the evidence to facilitate development of a framework of tailored information or decision aid, to enable effective collaborative decision-making; to facilitate truly informed choices; to improve the patient experience and to help acceptance and adjustment to life with technology.

Implications for practice and future research

1. Develop deeper understanding of individual and collective process of focused CRMD decision-making
2. Explore the potential influence of demographic and situational characteristics upon decision-making
3. Examine potential relationships between decision style and knowledge uptake
4. Develop, validate, apply and evaluate targeted information and support mechanisms
5. Develop method of assessing adequacy of knowledge and understanding to facilitate informed consent

Acknowledgements

Gratitude for the invaluable content expertise and personal perspectives upon preliminary findings contributed by a group of service users and carers is acknowledged.

Declaration of conflict of interest

The authors declare that there is no conflict of interest.

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Figures And Tables

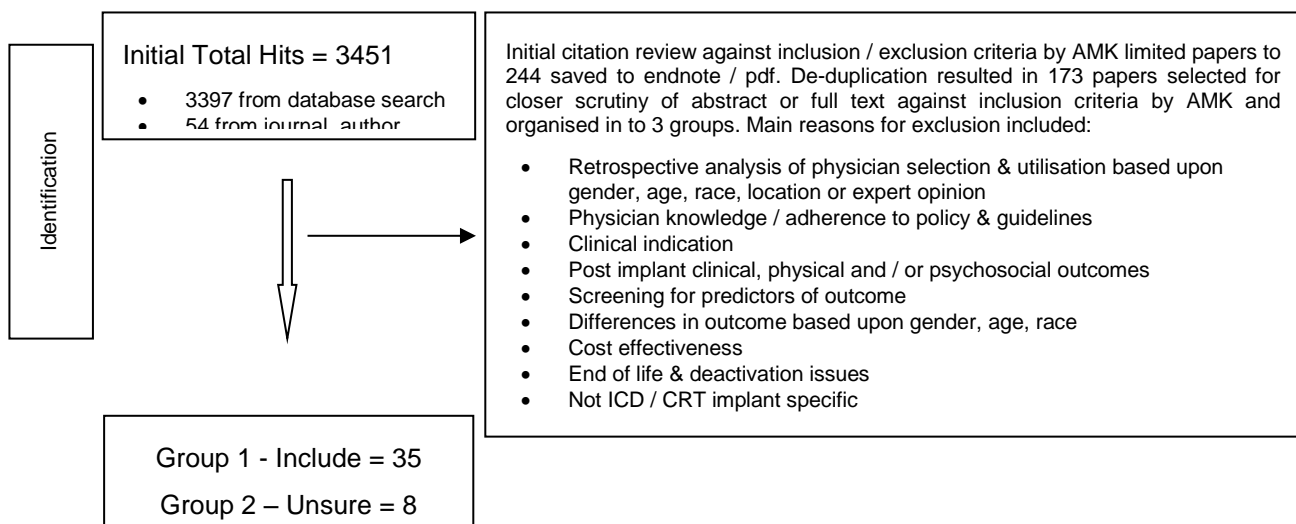
Table 1 Inclusion Criteria

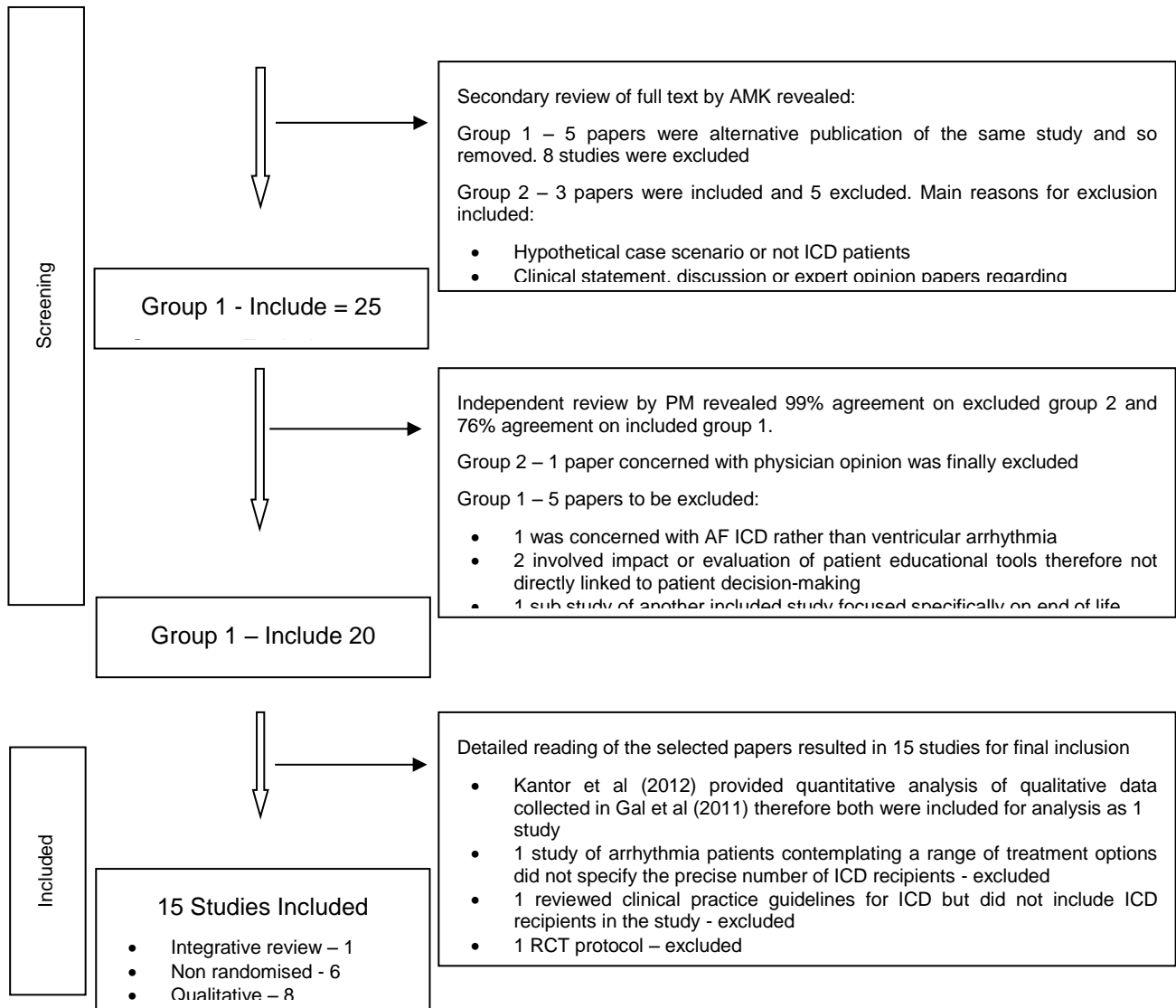
Table 1 Inclusion Criteria Applied To Scoping Review On Cardiac Patient Decision Making	
Included decision-making related to:	
i.	Patients with serious life threatening cardiac illness who meet selection criteria for ICD for secondary or primary prophylactic prevention of life threatening ventricular 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 eg 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 eg policy & guidance patient decision-making

Table 2 Data Sources Searched

Table 2 Data Sources Searched, Number Of Hits And Papers Retrieved From November 2014 to 2016	
<u>Databases</u>	<u>Papers Retrieved (Of Number of Hits)</u>
Cinahl (EBSCO Host)	41 (of 768 hits)
Embase (Embase 1996 to 2014 Week 47)	31 (1401)
Medline (MEDLINE(R) 1996 to November Week 2 2014)	45 (305)
Medline (MEDLINE(R) Limited 2014 to 2016)	1 (76)
PsycInfo (PsycINFO 1806 to November Week 4 2014)	13 (13)
Scopus (Health Sciences; Life Sciences; Social Sciences & Humanities)	13 (190)
Web of Science (All Databases)	44 (568)
Cochrane Library	2 (76)
Cochrane Database of Systematic Reviews	0 results
<u>Other</u>	
Journals	30
Reference Lists Of Citations & Full Text Articles	13
Author Search	3
Grey Literature	0
Cardiac Networks & Organisations, Policies & Guidelines	8
Totals	244 (of 3451)

Figure 1 Flow Diagram Of Study Selection Process





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 Statement¹¹⁶

Table 4 Emergent Clusters And Sub Themes

Table 4 Emergent Sub Themes Established Within The Clusters			
	Cluster And Sub Themes	Researcher	Study Aims And Findings
1	<p>Device knowledge acquisition and recall</p> <p>1.1 Insight Into Condition, Device Role And Function</p> <p>1.2 Physician Communication And Information Received</p>	<p>Chan et al., 2016⁵³ Non Randomised Descriptive</p> <p>Groarke et al., 2012⁵² Non Randomised Descriptive</p> <p>Hauptman et al., 2013⁵⁶ Non Randomised Descriptive</p>	<p>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.</p> <p>When asked about ICD function 52% correctly answered SCD prevention, 48% were not aware of SCD preventative role.</p> <p>Most feared consequence of heart failure was being bed bound (37%), breathlessness (30%), SCD (17%), chest pain (8%), don't know (8%)</p> <p>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%)</p> <p>Chan conclude that limited consultation time, language barriers, deep seated beliefs that contradict physician advise could explain lack of understanding</p> <p>Retrospective cohort study to explore the knowledge, understanding and view of patients with (primary/secondary) ICD or CRT device.</p> <p>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.</p> <p>Retrospective study to explore patient knowledge and physician communication of information during decision-making for cardiac device therapy (precise indication and device type unclear).</p> <p>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</p> <p>Prospective study to develop and test a measure (ICD-DAS) of patient evaluated ICD pros and cons and its impact upon</p>

			<p>patient decision-making for a primary ICD or CRT (precise indication and device type unclear).</p> <p>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.</p> <p>Prospective study to explore knowledge and influencing factors in decision to accept or decline primary ICD (precise indication and device type unclear).</p> <p>Hazleton et al., 2014⁵⁷ Non Randomised Descriptive 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.</p> <p>Singh et al., 2012⁶² Non Randomised Descriptive 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.</p> <p>Agard et al., 2007⁵¹ 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. 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 Limited information about device role, function & what they may expect. Some felt information was beyond their comprehension and most failed to seek additional information.</p> <p>Carroll et al., 2011⁵⁸ Grounded Theory 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.</p> <p>Lewis et al. (2014)⁴⁹ Integrative Review '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.</p> <p>Lucas 2012⁵⁴ Inaccurate perceptions of ICD-related risks and lifestyle limitations. Acceptors and decliners had reasonably good</p>
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		<p>Phenomenological</p> <p>Matlock et al., 2011⁶¹ Descriptive</p> <p>Ottenburg et al., 2014⁶⁴ Descriptive</p> <p>Yuhas et al., 2012⁵⁹ Grounded Theory</p>	<p>understanding of purpose & function of ICD</p>
2	<p>The Process Of Decision Making</p> <p>2.1 Approaches To Decision-making</p> <p>2.2 Factors Influencing The Decision Style</p> <p>2.3 Accepting Or Refusing Device Therapy</p>	<p>Agard et al., 2007⁵¹ Grounded Theory</p> <p>Carroll et al., 2011⁵⁸ Grounded Theory</p> <p>Gal et al., 2011⁵⁵ Grounded Theory</p>	<p>Explored patients with heart failure and previous life threatening arrhythmia experience and perception of role in secondary ICD decision-making.</p> <p>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.</p> <p>Negative experiences with ICD but did not regret implant decision because device increased chance of staying alive.</p> <p>Explored the decision-making process for patients who accepted and declined primary ICD</p> <p>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</p> <p>Explored the decision-making process for patients who had cardiac device therapy (precise indication & device type unclear).</p> <p>Reasons for choosing to accept - 2 key themes 1) Contributing factors; 2) Relationship to Dr / Doctor's role. Researchers grouped themes as 'active' relationship to DM & passivity. Those who described benefits of having ICD more likely to accept because 'peace of mind' 'safety net' (both considered to be active) and 'afraid to die' (passive).</p>

		<p>(& Kantor et al., 2012⁶⁶)</p> <p>Lucas 2012⁵⁴</p> <p>Phenomenological</p> <p>Matlock et al., 2010⁶³</p> <p>Descriptive</p> <p>Matlock et al., 2011⁶¹</p> <p>Descriptive</p> <p>Ottenburg et al., 2014⁶⁴</p> <p>Descriptive</p>	<p>Explored lived experience of older adults decision to accept primary or secondary ICD or CRT</p> <p>DM of older adults with ICD influenced by 1) trust & faith in physicians decision; 2) accepting device was necessary; 3) decision easy to make; 4) hope & 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 trigger then all adopt passive approach (not described as such by Lucas)</p> <p>Explored patients with heart failure perceptions of difficult decisions and factors that influenced treatment decision-making (most had ICD or CRT).</p> <p>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.</p> <p>Explored patient and physician perception of decision-making for patients who accepted and declined primary ICD (inc refusal of secondary ICD).</p> <p>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.</p> <p>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.</p> <p>Explored reasons why patients declined primary cardiac device therapy.</p> <p>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.</p> <p>Explored perception of primary ICD to understand barriers to acceptance for patients who accepted and declined primary ICD.</p> <p>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</p> <p>Explored demographic and social factors that influenced patients decision to decline</p>
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		<p>Chan et al., 2016⁵³ Non Randomised Descriptive</p>	<p>65% did not regret decision, remaining unwilling to accept, 35% might agree to ICD in the future. Those most likely to reconsider were employed (poss financial reasons), feared SCD the most and acknowledged ICD preventative role</p> <p>26 (35%) reported feeling frightened when informed of requirement for ICD. 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. 5 of subgroup of 25 (20%) stated physician recommendation as reason for implant. 93% satisfied with decision to accept ICD therapy.</p> <p>When ICD deemed urgent, pts particularly overwhelmed by pace of DM. Older participants frequently deferred decision to family members. Interactions brief & decisions made quickly with little time to understand the implications. Some discharged home to consider decision. Many struggled with competing view of ICD as security net and source of physical and psychosocial discomfort.</p>
		<p>Groarke et al., 2012⁵² Non Randomised Descriptive</p>	<p>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.</p> <p>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.</p>
		<p>Hauptman et al., 2013⁵⁶ Non Randomised Descriptive</p>	<p>Retrospective study to assess decision regret and evaluate psychometrics of the Decision Regret Scale (DRS) among ICD recipients.</p>
		<p>Lewis et al. 2014⁴⁹ Integrative Review</p>	<p>Amount of decision regret (no regret vs. regret) 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 significant predictors of decision regret; while adjusting for clinical and psychological variables. DRS psychometrically sound instrument for assessing decisional outcomes of ICD recipients</p>

		<p>Singh et al., 2012⁶² Non Randomised Descriptive</p> <p>Hickman et al., 2010⁶⁰ & 2012⁶⁵</p>	
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