Application to the Medical Advisory Committee – 1223

for insertion, replacement or removal of a cardiac resynchronisation therapy device capable of defibrillation (CRT-D) for mild chronic heart failure (NYHA II)

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EXECUTIVE SUMMARY

a. Details of the proposed medical service and its intended use on the MBS

SUBMISSION BACKGROUND AND RATIONALE

Cardiac resynchronisation therapy device capable of defibrillation (CRT-D) implantation is used for treatment of chronic heart failure. The 2006 MSAC assessment report of Implantable Cardioverter Defibrillators (ICD) for Prevention of Sudden Cardiac Death (MSAC Assessment Report 32) recommended the listing of CRT-D implantation on the MBS for patients with moderate to severe chronic heart failure (New York Heart Association (NYHA) class III or IV). Since then, strong evidence from randomised controlled trials (RCTs) has demonstrated that CRT-D implantation significantly reduces the risk of mortality and heart failure (HF) events in patients with mild chronic heart failure (NYHA class II).

PROPOSED CHANGE TO THE MBS LISTING

It is proposed that the current Medicare Benefits Schedule (MBS) listings used for insertion, removal, or replacement of a CRT-D (MBS item 38371) and associated leads (MBS items 38368 and 38354) should be modified to include patients with NYHA class II chronic heart failure despite optimised medical therapy, and who meet all of the following criteria:

- Sinus rhythm
- A LVEF of less than or equal to 30%
- A QRS duration of 150 ms or more

b. Clinical evaluation for the main indication

EFFICACY

Clinical evidence has shown that CRT-D device has greater efficacy than ICD technology in patients with NYHA class II chronic HF despite optimised medical therapy (OMT). In Australian clinical practice, CRT-D devices are most likely to replace ICD technology in this patient population.

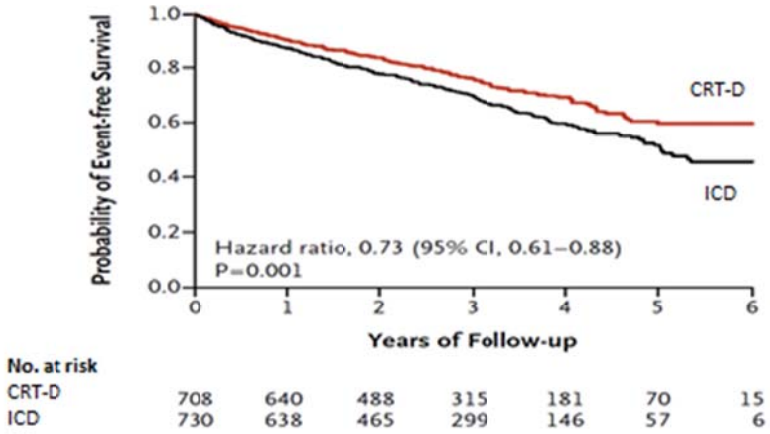
Two pivotal head-to-head, double blind, multicentre, parallel, randomised controlled trials, the RAFT trial and the MADIT-CRT trial, have been published reporting the efficacy of CRT-D compared with ICD in patients with NYHA class II HF despite optimised medical therapy (Tang et al 2010).

The RAFT trial compared CRT-D and ICD over a long duration of follow up (ie. a maximum of approximately 6 years) and included a patient population highly applicable to the proposed MBS patient population. The primary outcome measured in the RAFT trial was a composite measure of death from any cause or hospitalisation for heart failure. Within the ITT population included in the RAFT trial, death from any cause or hospitalisation for heart failure occurred in 33.2% of participants in the CRT-D group, compared to 40.3% of participants in the ICD group. CRT-D was estimated to reduce the risk of death or heart failure for hospitalisation by 25% (hazard ratio [HR], 0.75; 95% CI, 0.64 to 0.87; P<0.001).

In keeping with the findings in the ITT population, within the *a priori* identified subgroup of patients with NYHA class II heart failure, death from any cause or hospitalisation for heart failure occurred in

27.3% of participants in the CRT-D group, compared to 34.7% of those in the ICD group. As shown in **Figure b-1**, CRT-D was estimated to reduce the risk of death, or heart failure for hospitalisation, by 27% (HR, 0.73; 95% CI, 0.61 to 0.88); P = 0.001). At five years, the observed rate of death from any cause, or hospitalisation for heart failure, was 40.0% for CRT-D versus 48.1% for ICD (Tang et al 2010; RAFT CSR).

Figure b-1 Time to death from any cause or hospitalisation for heart failure in the RAFT trial (NYHA class II subgroup)



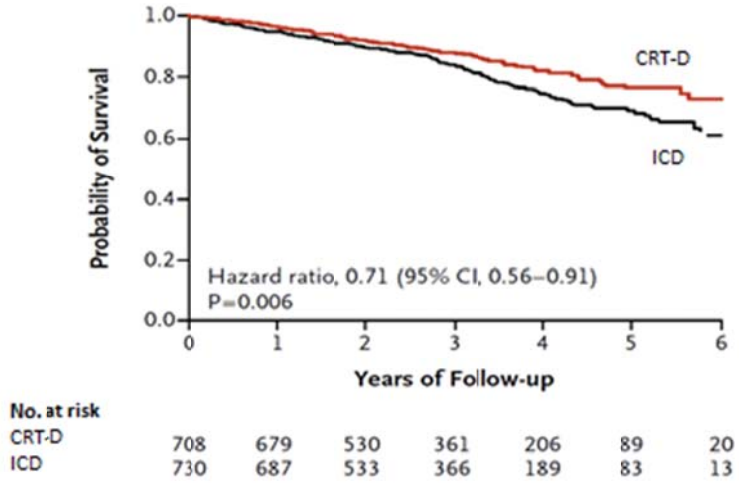
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010), Figure 2A

In the ITT population 186 of 894 (20.8%) participants in the CRT-D group died, compared with 236 of 904 (26.1%) participants in the ICD group. The five-year actuarial mortality rate was 28.6% for the CRT-D group versus 34.6% for the ICD group (HR, 0.75; 95% CI, 0.62 to 0.91; P=0.003).

Within the subgroup of patients with NYHA class II heart failure, 110 of 708 (15.5%) participants in the CRT-D group died, compared with 154 of 730 (21.1%) participants in the ICD group. Kaplan-Meier estimates of time to death from any cause for the subgroup of patients with NYHA class II heart failure are shown in **Figure b-2**. At five years, the all-cause mortality rate was 23.7% for CRT-D versus 31.0% for ICD (HR, 0.71; 95% CI, 0.56 to 0.91; P=0.006).

Therefore, for the ITT and the *a priori* specified NYHA class II HF subpopulation, treatment with CRT-D resulted in significantly lower rates of mortality and hospitalisation for heart failure compared with ICD.

Figure b-2 Time to death from any cause in the RAFT trial (NYHA class II subgroup)



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010), Figure 1C

SAFETY

The two clinical trials, RAFT and MADIT-CRT, provided evidence to suggest that in regards to safety, CRT-D is comparable with ICD. The RAFT trial reported one participant in the ICD arm of the RAFT trial that had died from worsening heart failure within 24 hours of device implantation. During the first 30 days after device implantation, there were 118 device- or implantation-related complications among the 888 participants who received a CRT-D implant, versus 61 among 898 participants in the ICD group.

In MADIT-CRT, system-related complication-free rate for participants in the CRT-D group was 84.8% with a lower one-sided 95% confidence bound of 82.9%. This was statistically significantly greater the pre-specified safety boundary of 70%, therefore it was concluded that CRT-D systems are safe in patients with NYHA class I or II heart failure, a LVEF of less than 30%, and QRS duration of 130 ms or more (MADIT-CRT CSR).

The REVERSE and MIRACLE ICD II double blind, multicentre, parallel randomised controlled trials were additionally identified to provide evidence supporting the safety of CRT-D devices. For REVERSE, complication rates did not differ between treatment groups (P=0.64) and were reported for the trial population as a whole. Of the 210 participants who underwent CRT-D implantation in the MIRACLE ICD II trial, 46 participants (22%) experienced 56 complications from the time of implant to discharge.

c. Synthesis with other evidence

SUMMARY OF THE RESULTS OF THE PRE-MODELLING STUDIES AND THEIR APPLICATION TO THE ECONOMIC MODEL

Table c-1 presents a summary of the four pre-modelling issues investigated and the application of the results of these studies in the economic evaluation presented in Section D of this submission.

Table c-1 Summary of the findings of the pre-modelling studies and their application to the economic evaluation

Description of pre-modelling issue	Section C cross-reference	Findings	Values used in the economic analysis	Section D cross-reference
Applicability of the trial based evidence to the proposed MBS indication and the economic analysis	Section C.1	The population that most closely matches the MBS indication sought for CRT-D and the economic evaluation presented herein was presented in the *a priori* identified NYHA II subgroup of the RAFT trial (Tang et al 2010)	Where available, data from the NYHA II *a priori* identified subgroup of patients in the RAFT trial were used to populate the economic model	**Section D.1-D.6** Step 1a, 1b, 1c, 2 and 3
Extrapolation of trial based evidence for all-cause mortality	Section C.2	A Weibull function accurately represents the survival of patients treated with an ICD in the RAFT trial. After application of the adjusted hazard ratio favouring CRT-D over ICD (0.71; 95% CI, 0.56-0.91, *p*=0.006) to the baseline hazard (ICD hazard) the survival benefit expected with CRT-D is also accurately represented.	A Weibull function (Gamma = 1.36 and Lambda 120.07) is used to represent the baseline hazard (ICD arm) of all-cause mortality in the economic model. The CRT-D all-cause mortality estimates are estimated by application of the adjusted HR (0.71) to the baseline hazard.	**Section D.1-D.6** Step 1b, 1c, 2 and 3
			An alternative model (exponential) is also fitted to the survival data to ascertain the impact this has on the incremental cost-effectiveness of CRT-D compared to ICD	**Section D.6** (Sensitivity analyses)
Preference-based health-related quality of life (utility estimates)	Section C.3	Utility weight estimates sourced directly from the MADIT-CRT RCT trial (Noyes et al 2013) appear consistent with those reported in other studies that have assessed utility weights in patients with mild chronic heart failure. As these utility weights are derived directly from an RCT comparing the treatments of interest they are simply applied directly to each arm of the economic model.	Baseline utility applied for first 6 months of economic model in both ICD and CRTD arms = 0.847 Utility weight applied to ICD arm from > 6 months = 0.876 Utility weight applied to CRT-D arm from > 6 months = 0.883	**Section D.1-D.6** Step 1c, 2 and 3

Description of pre-modelling issue	Section C cross-reference	Findings	Values used in the economic analysis	Section D cross-reference
Cost of optimised medical therapy	Section C.4	The annual cost of optimised medical therapy has been estimated using the methodology described in MSAC Assessment Report 32.	Annual cost of OMT applied to both arms of the economic model = $529.61	**Section D.1-D.6** Step 1a, 1b, 1c, 2 and 3

Abbreviations:CI,confidence interval; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; HR, hazard ratio; ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Scheme; MSAC, Medical Services Advisory Committee; NYHA, New York Heart Association; OMT, optimised medical therapy; RCT, randomised controlled trial

d. Economic evaluation for the main indication

COST PER PATIENT

The *cost per patient* of a successful CRT-D or ICD implantation is presented in a disaggregated form in **Table d-1**. The table also presents the bearer of each cost and the source of the cost estimate employed in the analysis.

The total cost of a successful CRT-D implantation procedure is $75,060.32 of which $2027.73 is incurred by Medicare and private health insurers for medical service fees.

The total cost of a successful ICD implantation procedure is $63,424.33 of which $1489.11 is incurred by Medicare and private health insurers for medical service fees.

Table d-1 Total cost per patient of a successful CRT-D or ICD implantation

Resource type	Unit price	Quantity (no)	% of fee claimable[a]	Cost per procedure	Bearer of cost	Source
Successful CRT-D implant procedure						
Medical services						
Insertion of LV lead (transvenous)[b]	$1,224.60	0.937	100%	$1,147.14	MBS/PHI	MBS 38368
Insertion of LV lead (epicardial)[b]	$1,224.60	0.063	100%	$77.46	MBS/PHI	MBS 38654
Insertion of defibrillator lead	$1,052.65	1	50%	$526.33	MBS/PHI	MBS 38384
Insertion of pacemaker lead	$638.65	1	25%	$159.66	MBS/PHI	MBS 38350
Insertion of CRT-D generator	$287.75	1	25%	$71.94	MBS/PHI	MBS 38371
Average cost of general anaesthesia (as reported in DAP)[c]	$226.00	0.2	100%	$45.20	MBS/PHI	DAP
Hospital services						
Hospitalisation for CRT-D implantation	$5,388.03	1	NA	$5,388.03	Private hospitals	Table D.4 5
System components						
LV lead	$6,240.00	1	NA	$6,240.00	PHI	Table D.4 2
Defibrillation lead	$9,000.00	1	NA	$9,000.00		
Pacemaker lead	$1,262.80	1	NA	$1,262.80		
CRT-D generator	$51,141.76	1	NA	$51,141.76		
Total cost per successful CRT-D implantation procedure				**$75,060.32**		

Resource type	Unit price	Quantity (no)	% of fee claimable[a]	Cost per procedure	Bearer of cost	Source
Successful ICD implant procedure						
Medical services						
Insertion of defibrillator lead	$1,052.65	1	100%	$1,052.65	MBS/PHI	MBS 38384
Insertion of pacemaker lead	$638.65	1	50%	$319.33	MBS/PHI	MBS 38350
Insertion of ICD generator	$287.75	1	50%	$71.94	MBS/PHI	MBS 38387
Average cost of general anaesthesia (as reported in DAP)[c]	$226.00	0.2	100%	$45.20	MBS/PHI	DAP
Hospital services						
Hospitalisation for ICD implantation	$4,863.52	1	NA	$4,863.52	Private hospitals	Table D.4 5
System components						
ICD generator	$45,158.60	1	NA	$46,808.89	PHI	Table D.4 2
Defibrillation lead	$9,000.00	1	NA	$9,000.00		
Pacemaker lead	$1,262.80	1	NA	$1,262.80		
Total cost per ICD implantation procedure				**$63,424.33**		

Abbreviations: DAP, Decision Analytic Protocol; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MBS, Medicare Benefits Schedule; PHI, Private health insurer

Source: Medicare Benefits Schedule (1 May 2013), DAP for MSAC Application 1223, Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'CRT-D implant costs' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

a The percentage of fee claimable is determined in accordance with the MBS Multiple Operation Rule (Table D-9).

b Proportion of patients receiving transvenous or epicardial insertion of the left ventricular lead is estimated in Table D-10**.**

c Based on clinical opinion it is assumed that 20% of patients undergoing CRT-D implantation will receive general anaesthesia and therefore require medical services performed by an anaesthetist. The average cost of an anaesthetist delivering general anaesthetic during CRT-D implantation is sourced from the Consultation DAP for MSAC Application 1223.

OVERVIEW OF THE ECONOMIC EVALUATION

The clinical evaluation presented previously demonstrates that CRT-D implantation significantly reduces the risk of all-cause mortality, cardiovascular mortality, and hospitalisation for heart failure, compared to ICD implantation, in the proposed patient population. Based on the fact that CRT-D has been shown to be clearly superior to ICD in direct head-to-head randomised controlled trials in terms of efficacy, the economic evaluation has been conducted as a cost-utility analysis that assesses the incremental cost-effectiveness of CRT-D compared to ICD.

A supplementary analysis in which all preference-based health-related quality of life weighting (utility) of survival was removed from the base case analysis (ie. a cost per life-year-saved analysis) was also performed.

The economic evaluation was developed in three discrete steps, presenting an incremental cost-effectiveness ratio (ICER) of CRT-D relative to ICD in each step. These steps are described below.

Step 1a

This step is a trial-based economic evaluation that estimates the incremental *cost per death avoided* for CRT-D compared with ICD over a 60-month period. This step uses the unadjusted 60 month survival data reported in NYHA II patients in the RAFT trial for each arm of the economic model (Tang et al 2010). This step includes direct initial intervention costs (i.e. costs associated with CRT-D implantation, ICD implantation and optimal medical therapy), follow-up monitoring costs, costs associated with hospitalisation for heart failure, and costs associated with device-related hospitalisations. Discounting is not applied in this analysis.

Step 1b

This step is identical to Step 1a except that the proportion of patients dying over the 60-month period is determined using a Weibull function to determine the baseline hazard of death in the ICD arm. The probability of death in this analysis is estimated in the CRT-D arm using the baseline hazard for the ICD modified by the adjusted all-cause mortality hazard ratio reported for the *a priori* identified NYHA II subgroup (HR, 0.71; 95% CI, 0.56 to 0.91; P=0.006). Discounting is not applied in this analysis.

Step 1c

This step is identical to Step 1b except that the outcome measures generated by the model in this step are converted into quality-adjusted life-years (QALYs). In this way the model generates an incremental cost per additional QALY gained for CRT-D treatment when compared to ICD treatment over a 60 month time horizon. Discounting of both costs and effects are applied in this analysis.

Step 2

This step is identical to Step 1c except that the time horizon of the economic analysis is extended to 20 years to provide a more complete description of the mean benefits CRT-D treatment offers over ICD treatment. This analysis also captures the cost of generator replacement due to battery depletion. Discounting of both costs and effects are applied in this analysis.

Step 3 (base case)

This step is identical to Step 2 except that the time horizon of the economic analysis is set to a life time analysis (a maximum cohort age of 100 years) to provide a more complete description of the mean benefits CRT-D treatment offers over ICD treatment over the cohort's lifetime. Step 3 is the base-case economic evaluation. It builds on Step 2 by extrapolating health outcomes and health care resource use over the lifetime of the model cohort. This step captures the long-term costs and consequences associated with CRT-D implantation, compared to ICD implantation. Discounting of both costs and effects are applied in this analysis.

A Markov cohort model was used to estimate costs and quality adjusted life years (QALYs) associated with CRT-D implantation, compared to ICD implantation, in patients with NYHA class II heart failure, who have sinus rhythm, a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more, despite optimised medical therapy. The base case analysis explored the cost-effectiveness of CRT-D over ICD over the patient's lifetime. A 5% discount rate was used for both costs and benefits and a health care system perspective was used in the model.

Clinical inputs were derived from the RAFT trial, while economic inputs were derived from the May 2013 Medicare Benefits Schedule (MBS), the May 2013 Pharmaceutical Benefits Schedule (PBS), and the National Hospital Cost Data Collection Cost Weights for Australian Refined Diagnosis Related Groups (AR-DRGs; Round 13, 2008-2009).

RESULTS: INCREMENTAL COSTS AND EFFECTIVENESS

Table d-2 presents the incremental cost-effectiveness ratio (ICER) estimates for each step of the economic analysis. In the base case analysis CRT-D is shown to be economically attractive compared to ICD at $27,737.11 per additional quality-adjusted life-year gained.

The base case economic analysis was most sensitive to changes in the estimates of all-cause mortality benefits associated with CRT-D treatment, the cost and duration of generator replacement

due to battery depletion and the preference-based health-related quality of life estimates applied in the analysis. Regardless, when reasonable extremes of these input parameters were applied to the analysis CRT-D remained economically attractive.

Table d-2 Incremental cost-effectiveness by model step

Resource item description	CRT-D	ICD	Incremental
Step 1a (Cost per death avoided at 60 months)			
Cost	$83,049.65	$70,688.15	$12,361.50
Effect (% Deaths)	23.7%	31.0%	7.3%
		Cost per death avoided	***$169,335.60***
Step 1b (Cost per death avoided at 60 months)			
Cost	$83,204.91	$70,849.26	$12,355.65
Effect (% Deaths)	24.1%	32.2%	8.1%
		Cost per death avoided	***$152,621.27***
Step 1c (Cost per QALY at 60 months)			
Cost	$82,288.57	$70,052.23	$12,236.34
Effect (QALYs)	3.500	3.332	0.169
		Cost per QALY	***$72,422.51***
Step 2 (Cost per QALY at 20 years)			
Cost	$136,148.01	$105,366.71	$30,781.30
Effect (QALYs)	6.784	5.781	1.003
		Cost per QALY	***$30,704.02***
Step 3 (Cost per QALY lifetime – base case)			
Cost	$138,665.26	$106,138.92	$32,526.34
Effect (QALYs)	7.059	5.886	1.173
		Cost per QALY	***$27,737.11***

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; QALYs, quality-adjusted life-years

Table d-3 presents a supplementary analysis in which all preference-based health-related quality of life weighting (utility) of survival is removed from the base case analysis (ie. a cost per life-year-saved analysis). This analysis generates an ICER of $25,445.66 per life-year-saved for CRT-D compared to ICD over the cohort's lifetime. This is a similar estimate to that generated by Step 3, albeit using a different outcome metric.

Table d-3 Supplementary cost-effectiveness analysis 1 (cost per life year saved)

Resource item description	CRT-D	ICD	Incremental
Supplementary economic analysis 1			
Cost	$138,665.26	$106,138.92	$32,526.34
Effect (Life-years-saved)	8.012	6.734	1.278
		Cost per life year saved	***$25,445.66***

e. Estimated extent of use and financial implications

UTILISATION

The net financial impact of implementing the reimbursement of CRT-D through the MBS was calculated using a market-share approach and was based on the comparison of two different scenarios:

- Scenario 1: CRT-D is reimbursed for patients with NYHA II heart failure with sinus rhythm LVEF of less than or equal to 30% and a QRS of 150 ms or more (i.e., world with CRT-D).
- Scenario 2: CRT-D is not reimbursed in this population (i.e., world without CRT-D).

To estimate market share, and what proportion of patients would receive CRT-D, seven KOLs were asked to estimate the proportion of patients that are currently eligible to receive MBS item 38387 that would meet the criteria to receive CRT-D (NYHA class II patients with a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more). Estimates ranged from 10% to less than 40% of patients, with 20% the most common response. Therefore, in the base case analysis, it was estimated that 20% of patients receiving MBS item 38387 would receive CRT-D. A sensitivity analysis is presented with the upper and lower ranges of estimates. The number of patients who received an ICD in Australia, reimbursed through the MBS, was 742 in 2012. This number of patients is expected to grow to 1208 by 2018, and therefore the number of patients expected to be treated with CRT-D would be 242 in 2018.

The overall net financial impact to healthcare is presented in **Table e-1**. The financial impact of introducing the CRT-D onto the MBS would be $73,972 in 2014 and grow to $97,582 in 2018 of which a portion would be funded by private health insurers. The net financial impact to healthcare is $2,064,177 in 2014 which is expected to increase to $2,722,999 in 2018. The device costs incurred by private health insurers' accounts for approximately 90% of the total net financial impact of reimbursing CRT-D in the newly proposed MBS indication.

Table e-1 Projected patient numbers and net Cost to healthcare

Description	2014	2015	2016	2017	2018
Number of patients treated with CRT-D	183	198	212	227	242
Net cost of medical services to the MBS and private health insurers	$73,972	$79,875	$85,777	$91,680	$97,582
Net cost to private hospitals	$96,114	$103,783	$111,452	$119,122	$126,791
Net cost to private insurers through prostheses list	$1,894,090	$2,045,224	$2,196,358	$2,347,492	$2,498,626
Net total cost to healthcare	**$2,064,177**	**$2,228,882**	**$2,393,588**	**$2,558,293**	**$2,722,999**

NB. Rounding applies
Abbreviations: MBS, Medicare Benefits Schedule

CONCLUSIONS

The clinical evaluation presented herein has demonstrated that CRT-D implantation significantly reduces the risk of all-cause mortality, cardiovascular mortality, and hospitalisation for heart failure, while displaying comparable safety compared to ICD implantation, in the proposed patient population. Further, a formal cost-utility analysis has shown that the CRT-D technology is cost-

effective costing $27,737 per additional quality-adjusted life-year gained. These benefits come at a small financial impact to the MBS and starting at $73,972 in 2014 and growing to $97,582 in 2018 of which a portion would be funded by private health insurers.

ABBREVIATIONS

6MWD	6-minute walk distance
ACE	angiotensin-converting-enzyme
AE	adverse event
AF	atrial fibrillation
ANOVA	analysis of variance
ARB	angiotension II receptor blocker
AR-DRG	Australian Refined Diagnosis Related Groups
BNP	B-type natriuretic peptide
CABG	coronary artery bypass graft
CI	confidence interval
CO	crossover
COPD	chronic obstructive pulmonary disease
CRT-D	cardiac resynchronisation therapy device capable of defibrillation
CRT-OFF	cardiac resynchronisation not activated
CRT-ON	cardiac resynchronisation activated
CRT-P	cardiac resynchronisation therapy pacemaker
CUA	cost-utility analysis
DAP	Decision Analytic Protocol
DB	double blind
ECG	electrocardiography
EQ-5D	EuroQol-5 Dimensions
FU	Follow up
HR	hazard ratio
HRQoL	health-related quality of life
HUI3	health utilities index mark 3
ICD	implantable cardioverter-defibrillator

ICER	Incremental cost-effectiveness ratio
ITT	intention-to-treat
IVMD	intraventricular mechanical delay
JVP	jugular venous pressure
KCCQ	Kansas City Cardiomyopathy Questionnaire
KM	Kaplan Meier
LBBB	left bundle branch block
LOCF	lost observation carried forward
LV	left ventricular
LVEDV	left ventricular end diastolic function
LVEDVI	left ventricular end diastolic volume-index
LVEF	left ventricular ejection fraction
LVESV	left ventricular end systolic function
LVESVI	left ventricular end systolic volume-index
LYS	life year saved
MBS	Medicare Benefits Schedule
MC	multicentre
MCID	minimal clinically important difference
MI	myocardial infarction
MLWHF	Minnesota Living with Heart Failure Questionnaire
MMRM	mixed methods repeated measures
ms	milliseconds
MSAC	Medical Services Advisory Committee
NA	not applicable
NICE	National Institute for Health and Care Excellence
NIVCD	non-specific intraventricular conduction delay
NR	not reported
NT-proBNP	N-terminal prohormone of brain natriuretic peptide

NYHA	New York Heart Association
OMT	optimal medical therapy
PBS	pharmaceutical benefits scheme
PG	parallel group
PGA	Patient's Global Assessment
PICO	Population
PL	Prostheses List
PND	paroxysmal nocturnal dyspnoea
PP	per-protocol
QALY	Quality adjusted life year
R	randomised
RA	right atrial
RCT	randomised controlled trial
RR	relative risk
RV	right ventricular
SAE	serious adverse event
SCD	sudden cardiac death
SD	standard deviation
SEM	standard error of the mean
SF-36	Short Form 36 Health Survey
SF-6D	Short Form 6 dimensions
SG	standard gamble
SRC	system-related complication
TGA	Therapeutic Goods Administration
TTO	time-trade-off
VCO_2/VO_2	respiratory gas exchange ratio
VO_2	peak oxygen consumption

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ABBREVIATIONS XI

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A DETAILS OF THE PROPOSED MEDICAL SERVICE AND ITS INTENDED USE ON THE MBS

A.1 ITEMS IN THE DECISION ANALYTIC PROTOCOL

This application assesses the safety, effectiveness and cost-effectiveness of implantation of a cardiac resynchronisation therapy device capable of defibrillation (CRT-D) in New York Heart Association (NYHA) class II heart failure patients (with sinus rhythm, a left ventricular ejection fraction (LVEF) of less than or equal to 30%, and a QRS duration of greater than or equal to 150 ms). It is based on a Decision Analytic Protocol (DAP) provided by the Protocol Advisory Sub Committee of the Medical Services Advisory Committee (MSAC).

Three research questions are presented on page 43 of the final Decision Analytic Protocol (DAP). Each research question along with a brief discussion of the information currently available to address that question is presented below.

Research question 1

What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II heart failure patients (with sinus rhythm, LVEF of no more than 30%, and a QRS duration of 150 ms or greater) compared with ICD?

This research question identifies the patient population that is the primary focus of this submission.

Research question 2

What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II heart failure patients (with LVEF of no more than 30%, and a QRS duration of 150 ms or greater) with atrial fibrillation compared with ICD?

This research question identifies a sub-population of patients. Research into the benefits of CRT-D in this patient population is ongoing and the benefits of CRT-D treatment compared with ICD treatment in this patient population are preliminary in nature at this stage. The Sponsors wish to indicate that they are not seeking reimbursement in this patient population at this time.

Research question 3

What is the safety, effectiveness, and cost-effectiveness of a CRT-D in NYHA class II heart failure patients (with sinus rhythm, LVEF of less than or equal to 35%, and a QRS duration of 150 ms or greater) compared with ICD?

This research question identifies a slightly broader patient population than presented in research question 1.There is compelling evidence which lead to the current MBS item for CRT-D in patients with LVEF< 35% (albeit in NYHA Class III/IV) and the current submission is built upon strong clinical evidence for CRT-D in patients with LVEF <30%. While NYHA Class II patients with LVEF between 30 and 35% have not specifically been the focus of clinical trials, there is no evidence to indicate that these patients would not benefit from CRT-D therapy.

Other items

The final DAP appears to have different reimbursement fees listed for the current and proposed MBS Item numbers. The correct values are listed in Table A-2, Table A-4 and Table A-6 of this submission. The Sponsor respectfully requests that these values be corrected.

The final DAP has omitted the VIVA range of CRT-D devices (Medtronic) which have recently been included on the prosthesis list. The Sponsor respectfully requests that this omission is rectified.

A.2 PROPOSED MEDICAL SERVICE

The proposed medical service is a surgical procedure for the insertion, replacement, or removal of a CRT-D in patients with mild chronic heart failure (NYHA class II) who meet certain criteria. This intervention is currently listed on the Medicare Benefits Schedule (MBS) for patients with moderate to severe disease (NYHA class III or IV) (MBS item numbers 38371, 38368 and 38654).

A.2.1 Health problem to be addressed

The 2006 MSAC assessment report of Implantable Cardioverter Defibrillators for Prevention of Sudden Cardiac Death (MSAC Assessment Report 32[54]) recommended the listing of CRT-D implantation on the MBS for patients with moderate to severe chronic heart failure (NYHA class III or IV). Since then, strong evidence from randomised controlled trials (RCTs) has demonstrated that CRT-D implantation significantly reduces the risk of mortality and heart failure events in patients with mild chronic heart failure (NYHA class II) and a LVEF of less than or equal to 30%. The clinical efficacy of CRT-D appears to be greatest in patients with a QRS duration of 150 ms or more (**Section B**).

This application seeks to align the MBS listings for insertion, removal and replacement of a CRT-D with the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand Guidelines for the Prevention, Detection and Management of Chronic Heart Failure in Australia (NHFA/CSANZ 2011[59]).

Specifically, it is proposed that the current MBS listings used for insertion, removal, or replacement of a CRT-D and associated leads should be modified to include patients with NYHA class II chronic heart failure despite optimised medical therapy, and who meet all of the following criteria:

- Sinus rhythm
- A LVEF of less than or equal to 30%
- A QRS duration of 150 ms or more

These patients experience symptoms such as fatigue, palpitation, dyspnoea or angina pectoris, as a result of ordinary physical activity. The presence of sinus rhythm indicates that they do not have AF, a LVEF of less than or equal to 30% indicates severe left ventricular systolic dysfunction (LVSD), and a QRS duration greater than or equal to 150 ms indicates prolonged intraventricular conduction delay. These patients have impaired quality of life and a high risk of death from cardiovascular causes. Current clinical practice guidelines recommend considering CRT-D implantation to reduce the risk of mortality and heart failure progression in this patient group (NHFA/CSANZ 2011[59]; European Society of Cardiology 2012[28]; ACCF/AHA/HRS 2012[5]). Slowing the progression of heart failure disease using CRT-D is also likely to reduce morbidity and improve patient preference-based health-related quality of life (utility) and reduce the costs associated with worsening heart disease.

A.2.2 Description of the proposed medical service

CRT-D implantation typically involves insertion of a small battery-powered electrical impulse generator in the upper chest, with placement of three electrode leads that connect the generator to the heart. The right atrial lead is used for sensing and pacing; the right ventricular lead is used for sensing, pacing, defibrillation and/or cardioversion; and the left ventricular lead is used for cardiac resynchronisation. All three leads are inserted into the heart via the subclavian vein (or the cephalic or internal jugular vein in some cases), however specialised techniques are required to thread the left ventricular lead through the coronary sinus, and correctly position this lead inside a coronary vein.

The specific medical services that will be used for insertion, removal, or replacement of a CRT-D device in the requested MBS population are the same as those currently used for insertion, removal, or replacement of a CRT-D device in patients with NYHA class III or IV heart failure (MBS item numbers 38371, 38368, 38354, and 38350). All aspects of service delivery, including the clinical setting, staff requirements, equipment, facilities, and location will remain the same. As in current practice, the insertion, removal or replacement of a CRT-D device will be performed by a group of professionals, which may include an electrophysiologist, radiographer, cardiologist, cardiac surgeon, circulating nurse or scrub nurse.

Ordinarily, CRT-D generators are only replaced when the battery is exhausted, or at the clinicians discretion. Current implanted device batteries typically last between 5 and 8 years, depending on the demand for pacing, resynchronisation, and defibrillation in a particular patient. Complications such as lead dislodgement or lead failure occur infrequently.

A.2.3 Registration status

All CRT-D systems are intended to provide atrial pacing and/or ventricular antibradycardia and/or antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias, as well as biventricular pacing for cardiac resynchronisation therapy. The registration details of CRT-D generators and electrode leads that are currently listed on the Australian Register of Therapeutic Goods (ARTG) are summarised in **Appendix A**. All current and future CRT-D generators or leads are likely to be implanted using the medical services described above. Current and future CRT-D generators and leads that are not specifically listed on the ARTG should not be excluded from the MBS if their indication for use includes patients with NYHA II heart failure. Biotronik, Boston Scientific, Medtonic and St Jude Medical do not promote the use of their products outside the approved labelling.

The registered indications for CRT-D products in Australia are as follows:

- Biotronik CRT-D devices are indicated for treating life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation. Triple-chamber devices are indicated for patients with risk of sudden cardiac death caused by ventricular arrhythmias and risk of congestive heart failure with ventricular asynchrony. They are also indicated for primary prophylaxis in congestive heart failure patients.
- Boston Scientific CRT-D devices are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy and have LVEF ≤ 35% and QRS duration ≥ 120 ms. Boston Scientific is in the process of updating the registration labeling for CRT-D devices to include patients with mild heart failure (NYHA II) who remain symptomatic despite stable, optimal heart failure drug therapy and have LVEF ≤ 30% and QRS duration ≥ 150 ms.
- Medtronic CRT-D devices are indicated for use in patients who are at high risk of sudden death due to ventricular tachyarrhythmias and who have heart failure with ventricular dyssynchrony. These devices are intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias.
- St Jude Medical CRT-D devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening arrhythmias. CRT-D devices are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

Appendix 2 provides a full list of the CRT-D generators and leads that are currently included on the Prosthesis List. The differences in the benefits associated with specific CRT-D system components

reflect the fact that some components provide advanced functionality (e.g. auto test sensing parameters, auto capture threshold testing, lead impedance testing, or wireless remote analysis). All devices are inserted, removed, and replaced using the medical services described in **Section A.2.2**.

A.3 CURRENT AND PROPOSED ARRANGEMENTS FOR PUBLIC REIMBURSEMENT

Insertion, removal or replacement of CRT-D generator

Medical services relating to the insertion, removal, or replacement of a CRT-D generator are currently reimbursed under MBS item number 38371, for patients with NYHA class III or IV heart failure, who have sinus rhythm , a LVEF of less than or equal to 35%, and a QRS duration of 120 ms or more, despite optimised medical therapy.

It is proposed that this MBS item number should be modified to also include patients with NYHA class II heart failure despite optimised medical therapy, and who meet all of the following criteria:

- Sinus rhythm
- A LVEF of less than or equal to 30%
- A QRS duration greater than or equal to 150 ms

The current and proposed MBS item descriptors for the insertion, removal, or replacement of a CRT-D generator are shown in **Table A-1** and **Table A-2.**

Table A-1 Current MBS item descriptor for insertion, removal, or replacement of a CRT-D generator

Category 3 – Therapeutic procedures
MBS 38371 PERMANENT CARDIAC SYNCHRONISATION DEVICE CAPABLE OF DEFIBRILLATION, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 35% o a QRS duration greater than or equal to 120 ms. Multiple Services Rule (Anaes.) Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70 Item 38371 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device capable of defibrillation inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Source: Medicare Benefits Schedule, May 2013[9]

Table A-2 Proposed MBS item descriptor for insertion, removal, or replacement of a CRT-D generator

Category 3 – Therapeutic procedures
MBS 38371 (proposed) PERMANENT CARDIAC SYNCHRONISATION DEVICE CAPABLE OF DEFIBRILLATION, insertion, removal or replacement of, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 35% o a QRS duration greater than or equal to 120 ms. And for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 30% o a QRS duration greater than or equal to 150 ms. Multiple Services Rule (Anaes.) Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70 Item 38371 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device capable of defibrillation inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Insertion, removal or replacement of the left ventricular electrode lead

Medical services relating to the insertion, removal, or replacement of the left ventricular electrode lead are also reimbursed for patients with NYHA class III or IV heart failure, who have sinus rhythm , a LVEF of less than or equal to 35%, and a QRS duration of 120 ms or more, despite optimised medical therapy. MBS item number 38368 covers transvenous insertion, removal or replacement of a left ventricular electrode lead via the coronary sinus and MBS number 38654 covers insertion, removal or replacement of a left ventricular electrode lead via open thoracotomy. Both of these item numbers can be used in conjunction with MBS item number 38371 for CRT-D implantation, therefore both will need to be modified to also include patients with NYHA class II heart failure. The current and proposed MBS item descriptors for MBS item numbers 38386 and 38354 are shown below.

Table A-3 Current MBS item descriptor for transvenous insertion, removal or replacement of a left ventricular electrode lead via the coronary sinus

Category 3 – Therapeutic procedures
MBS 38368 PERMANENT TRANSVENOUS LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of through the coronary sinus, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 35% o a QRS duration greater than or equal to 120 ms. Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which item numbers 38200 and 35200 apply. Multiple Services Rule (Anaes.) Fee: $1224.60 Benefit: 75% = $918.45 Item 38368 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Source: Medicare Benefits Schedule, May 2013[9]

Table A-4 Proposed MBS item descriptor for transvenous insertion, removal or replacement of a transvenous left ventricular electrode lead via the coronary sinus

Category 3 – Therapeutic procedures
MBS 38368 (proposed) PERMANENT TRANSVENOUS LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of through the coronary sinus, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 35% o a QRS duration greater than or equal to 120 ms. And for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 30% o a QRS duration greater than or equal to 150 ms. Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which item numbers 38200 and 35200 apply. Multiple Services Rule (Anaes.) Fee: $1224.60 Benefit: 75% = $918.45 Item 38368 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Table A-5 Current MBS item descriptor for insertion, removal or replacement of a left ventricular electrode by open thoracotomy

Category 3 – Therapeutic procedures
MBS 38654 PERMANENT LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of via open thoracotomy, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria: o Sinus rhythm o A left ventricular ejection fraction of less than or equal to 35% o A QRS duration greater than or equal to 120 ms. Multiple Services Rule (Anaes.)(Assist.) Fee: $1224.60 Benefit: 75% = $918.45 Item 38654 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Source: Medicare Benefits Schedule, May 2013[9]

Table A-6 Proposed MBS item descriptor for insertion, removal or replacement of a left ventricular electrode via open thoracotomy

Category 3 – Therapeutic procedures
MBS 38354 (proposed) PERMANENT LEFT VENTRICULAR ELECTRODE, insertion, removal or replacement of via open thoracotomy, for the purpose of cardiac resynchronisation therapy, for patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet the following criteria: o Sinus rhythm o A left ventricular ejection fraction of less than or equal to 35% o A QRS duration greater than or equal to 120 ms. And for patients who have mild chronic heart failure (NYHA class II) despite optimised medical therapy and who meet all of the following criteria: o sinus rhythm o a left ventricular ejection fraction of less than or equal to 30% o a QRS duration greater than or equal to 150 ms. Where the service includes right heart catheterisation and any associated venogram of left ventricular veins. Not being a service associated with a service to which item numbers 38200 and 35200 apply. Multiple Services Rule (Anaes.)(Assist.) Fee: $1224.60 Benefit: 75% = $918.45 Item 38354 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Insertion, removal or replacement of the right atrial and right ventricular leads

CRT-D implantation also requires the insertion of a defibrillation lead in the right ventricle and insertion of a pacemaker lead in the right atrium. These procedures are currently funded for patients in the proposed MBS population (MBS item numbers 38384 and 38350), therefore no modifications to these listings are required.

Table A-7 Current MBS item descriptor for insertion of defibrillation electrode lead

Category 3 – Therapeutic procedures
MBS 38384 AUTOMATIC DEFIBRILLATOR, insertion of patches for, or insertion of transvenous endocardial defibrillation electrodes for, primary prevention of sudden cardiac death in: o patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or o patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies. Multiple Services Rule (Anaes.)(Assist.) Fee: $1052.65 Benefit: 75% = $789.50 85% = $978.15 Item 38654 applies only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had a CRT device and transvenous left ventricular electrode inserted and who prior to its insertion met the criteria and now need the device to be replaced.

Source: Medicare Benefits Schedule, May 2013[9]

Table A-8 Current MBS item descriptor for insertion of pacemaker electrode lead

Category 3 – Therapeutic procedures
MBS 38350 SINGLE CHAMBER PERMANENT TRANSVENOUS ELECTRODE, insertion, removal or replacement of, including cardiac electrophysiological services where used for pacemaker implantation. Multiple Services Rule (Anaes.) Fee: $638.65 Benefit: 75% = $479.00 The fees for the insertion of a pacemaker (Items 38350, 38353 and 38356) cover the testing of cardiac conduction or conduction threshold, etc related to the pacemaker and pacemaker function. Accordingly, additional benefits are not payable for such routine testing under item 38209 or 38212 (Cardiac electrophysiological studies).

Source: Medicare Benefits Schedule, May 2013[9]

The proposed eligibility for CRT-D implantation in NYHA II patients requires measurement of LVEF and QRS duration and determining the presence of sinus rhythm. These assessments are already part of standard practice for the assessment of chronic heart failure patients. The proposed restriction for the listing of CRT-D in NYHA II patients who have not responded to medical therapy prevents the potential for inappropriate medicalisation of a previously untreated condition.

A.4 COMPARATOR DETAILS

The main comparator for this assessment is the insertion, removal, or replacement of an implantable-cardioverter defibrillator (ICD), as this is the medical service that healthcare providers would most likely replace if the current MBS listings for insertion, removal, or replacement of a CRT-D are modified to include the proposed MBS population. In current Australian practice, patients with NYHA class II heart failure and a low LVEF are much more likely to receive an ICD than to receive a CRT-P or remain on medical therapy alone, due to their increased risk of sudden cardiac death (SCD).

The surgical procedures used for ICD implantation are similar to those used for CRT-D implantation, however, ICD implantation does not require the insertion of a left ventricular lead through the coronary sinus. MBS item number 38387 is used for the insertion, removal, or replacement of an ICD generator (**Table A-9**). MBS item number 38384 is used for insertion of a defibrillation lead in the right ventricle (**Table A-7**) and MBS item number 38350 (**Table A-8**) is used for insertion of a defibrillation lead in the right atrium.

Table A-9 Current MBS item descriptor for insertion, removal or replacement of an ICD generator

Category 3 – Therapeutic procedures
MBS 38387 AUTOMATIC DEFIBRILLATOR GENERATOR, insertion or replacement of for, primary prevention of sudden cardiac death in: o patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or o patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. Not being a service associated with a service to which item 38213 applies, not for defibrillators capable of cardiac resynchronisation therapy. Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70 Multiple Services Rule (Anaes.)(Assist.) Fee: $287.85 Benefit: 75% = $215.90 85% = $244.70

Source: Medicare Benefits Schedule, May 2013[9]

A.5 CLINICAL MANAGEMENT ALGORITHMS

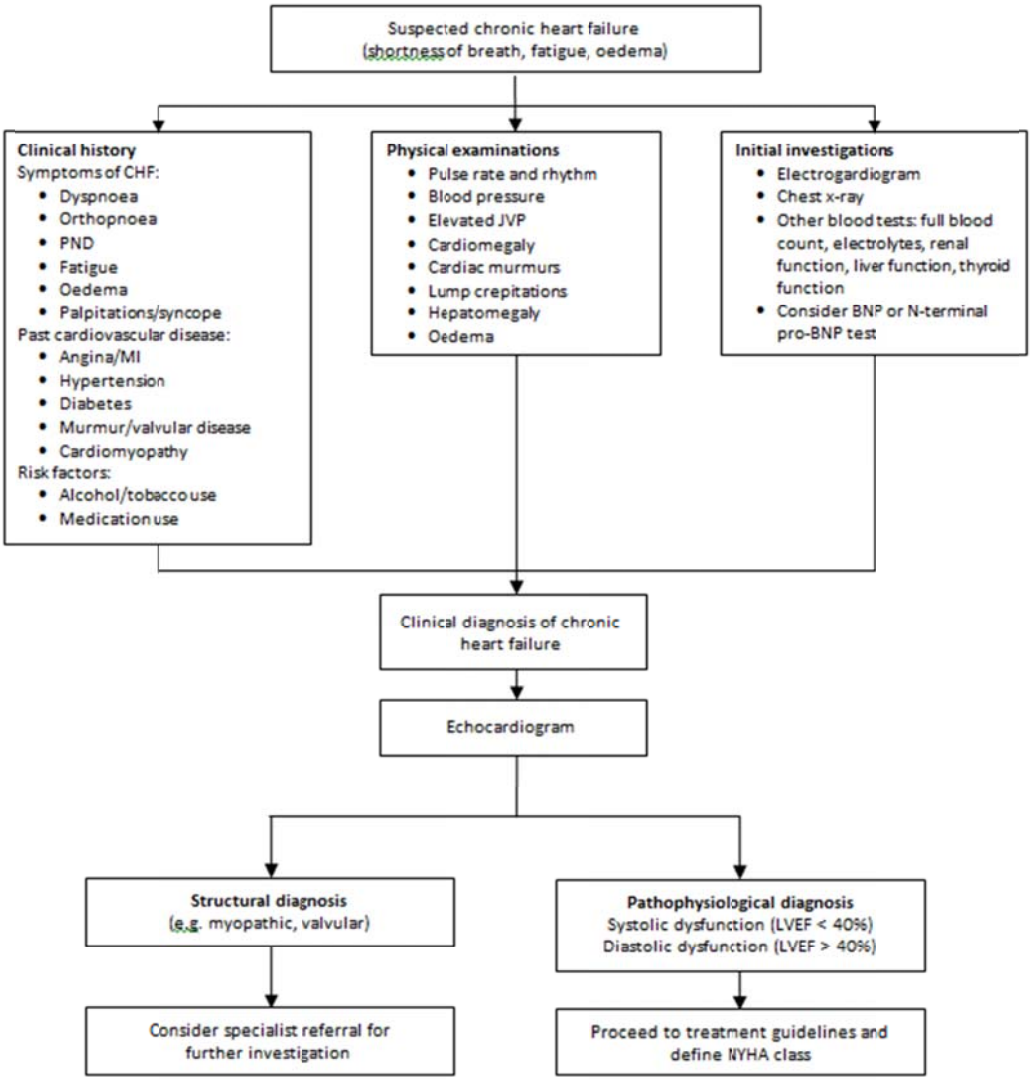
This application proposes that CRT-D will be a direct substitute for ICD in patients with NYHA class II heart failure, who have sinus rhythm, an LVEF of less than or equal to 30%, and a QRS duration greater than or equal to 150 ms despite optimised medical therapy. The clinical management algorithms presented below are based on current evidence-based clinical practice guidelines for the prevention, detection and management of chronic heart failure in Australia (NHFA/CSANZ 2011[59]), and are identical to those set out in the DAP.

Figure A-1 shows the recommended algorithm for diagnosis of chronic heart failure in Australia. This involves comprehensive assessment of a patient's clinical history, physical examinations, and investigative procedures. Trans-thoracic echocardiography is used to distinguish between heart failure due to systolic dysfunction, heart failure due to diastolic dysfunction, and heart failure due to a structural defect (e.g. cardiomyopathy or valvular disease) (NHFA/CSANZ 2011[59]). These initial assessments provide necessary information to determine whether a patient meets the sinus rhythm, LVEF, and QRS duration criteria for eligibility for CRT-D, ICD and CRT implantation. They are already performed as part of the initial pathway for diagnosis of heart failure, and will not be affected by the proposed changes to the MBS listings for CRT-D implantation.

Figure A-2 and **Figure A-3** show the current and proposed clinical management algorithms for management of patients with NYHA class II heart failure. It is expected that the majority of patients who meet the proposed eligibility criteria will receive CRT-D implantation, however due to comorbidities and other clinical factors, some patients may receive ICD instead of CRT-D, and some will continue to receive optimised medical therapy alone (ie. those contraindicated to surgery).

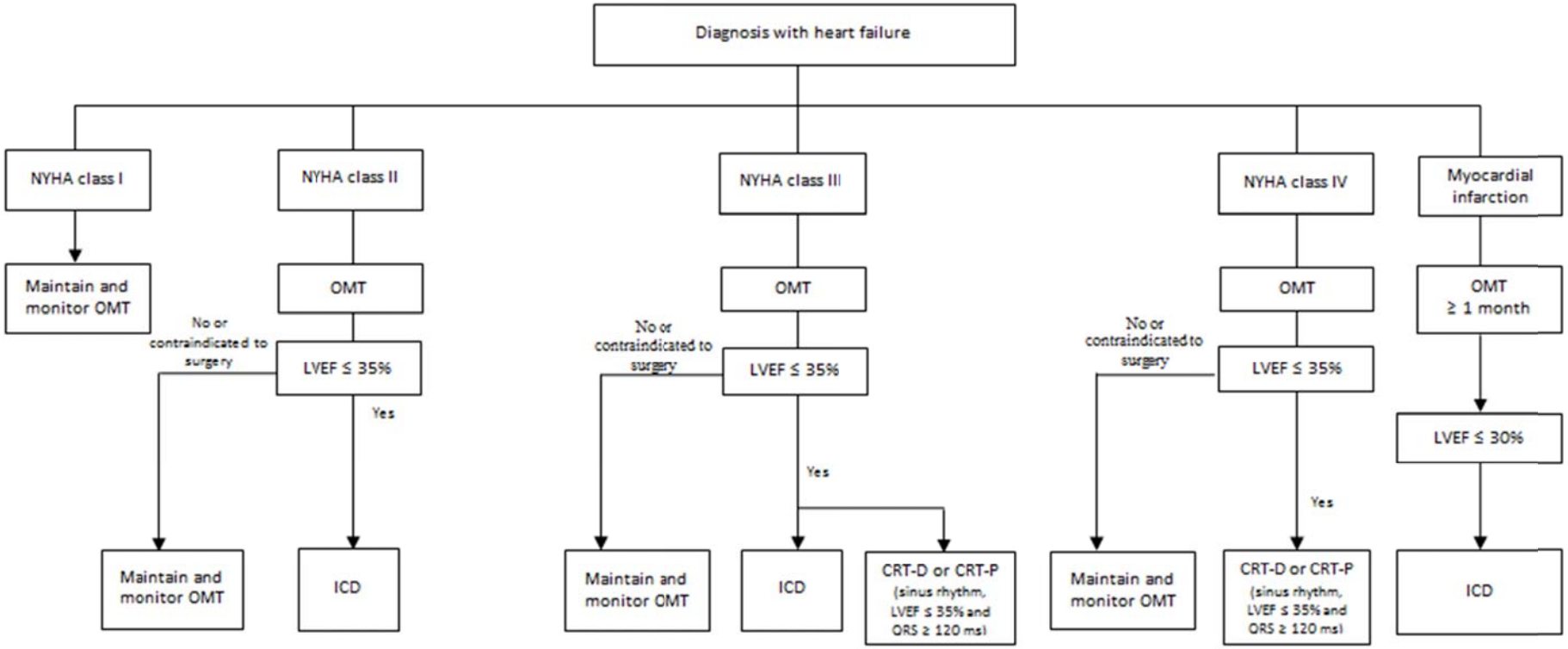
Ongoing monitoring is required for all patients with ICD and CRT-D devices, and services are provided both by physicians and product specialists. Device checks are usually performed every six months, but can be more frequent in patients experiencing problems, or when batteries/generators are nearing their expected end of life. Such checks can be performed at face-to-face visits or through remote monitoring. The nature and frequency of follow-up will not change with the introduction of the proposed medical services. The same MBS item number is used for monitoring of all patients with a CRT-D or ICD implant (MBS item number 11727). Chronic heart failure patients who have not undergone a device implantation would not have to undergo monitoring of an implanted device.

Figure A-1 Clinical algorithm for diagnosis of NYHA class II, III or IV heart failure in Australia



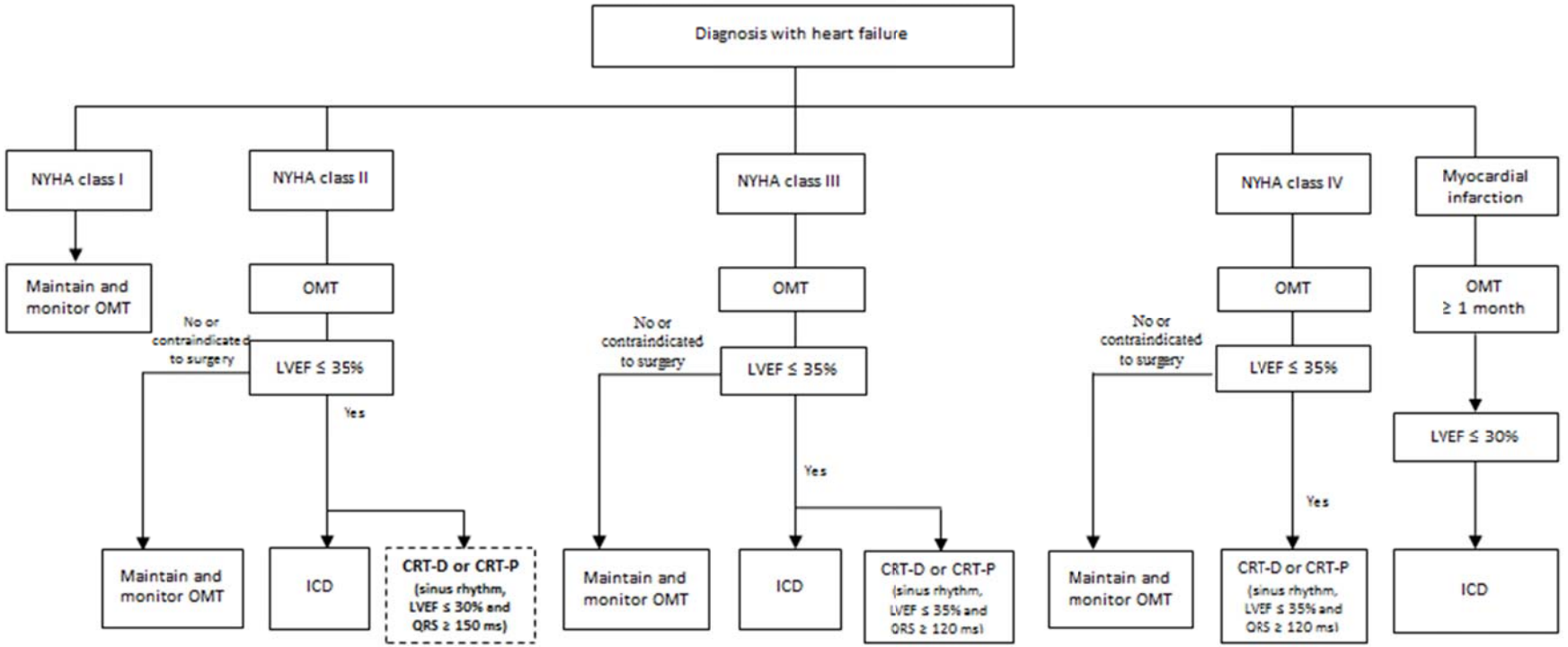
Source: NHFA/CSANZ (2011), p. 14, Figure 4.1[59]
Abbreviations: BNP, B-type natriuretic peptide; JVP, jugular venous pressure; LVEF, left ventricular ejection fraction; PND, paroxysmal nocturnal dyspnoea

Figure A-2 Current clinical algorithm for management of heart failure



Abbreviations: CRT-D cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; OMT, optimised medical therapy

Figure A-3 Proposed clinical algorithm for management of chronic heart failure



Abbreviations: CRT-D cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; OMT, optimised medical therapy

A.6 DIFFERENCES BETWEEN THE PROPOSED MEDICAL SERVICE AND THE MAIN COMPARATOR

Table A-10 shows a comparative summary of the indications, contraindications and adverse events associated with CRT-D and ICD implantation in patients with chronic heart failure. The key difference between these procedures is that CRT-D implantation provides cardiac resynchronisation and requires the insertion of a left ventricular electrode lead via the coronary sinus, while ICD implantation does not.

Table A-10 Key differences between CRT-D and ICD

Category	CRT-D	ICD
Indication	CRT-D therapy is indicated for atrial and/or ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening atrial and/or ventricular arrhythmias. Cardiac resynchronisation features are intended to restore synchronous contraction of the right and left ventricles in patients with a prolonged QRS duration.	ICD therapy is intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of life-threatening atrial and/or ventricular tachyarrhythmias.
Contraindications	CRT-D implantation is contraindicated in patients with ventricular tachyarrhythmias resulting from transient or correctable factors (e.g. drug toxicity, electrolyte imbalance, or acute myocardial infarction). Some devices are contraindicated for patients who have incessant ventricular tachycardia or ventricular fibrillation, or those whose primary disorder is chronic atrial tachyarrhythmia with no concomitant ventricular tachycardia or ventricular fibrillation.	ICD implantation is contraindicated in patients with ventricular tachyarrhythmias resulting from transient or correctable factors (e.g. drug toxicity, electrolyte imbalance, or acute myocardial infarction). Some devices are contraindicated for patients who have incessant ventricular tachycardia or ventricular fibrillation, or those whose primary disorder is chronic atrial tachyarrhythmia with no concomitant ventricular tachycardia or ventricular fibrillation.
Current MBS reimbursement	The insertion, removal, or replacement of a CRT-D is currently reimbursed for patients with moderate to severe chronic heart failure (NYHA class III or IV) who meet all of the following criteria, despite optimised medical therapy: • Sinus rhythm • A LVEF of less than or equal to 35% • A QRS duration greater than or equal to 120 ms	The insertion, removal, or replacement of a ICD is currently reimbursed for primary prevention of sudden cardiac death in: • Patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or • Patients with chronic heart failure associated with mild to moderate symptoms (NYHA class II or III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy.
Adverse events	Potential adverse events include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, lead or accessory breakage, and surgical complications such as haematoma, infection, inflammation, and thrombosis. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.	Potential adverse events include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, lead or accessory breakage, and surgical complications such as haematoma, infection, inflammation, and thrombosis. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association

A.7 CLINICAL CLAIM

This application presents the claim that CRT-D implantation is clinically superior to ICD implantation in the proposed MBS population. This claim is based on a systematic review of direct comparative randomised trials that compared CRT-D with ICD in patients with NYHA class II heart failure. The cost-effectiveness of CRT-D versus ICD therapy has been evaluated as a cost-utility analysis.

A.8 PRIMARY ELEMENTS OF THE DECISION ANALYSIS (PICO)

The Population, Intervention, Comparator and Outcomes (PICO) criteria defined by the DAP for this application are summarised in **Table A-11**.

Table A-11 PICO criteria for the main clinical research question

Category	Criteria
Population	Patients with mild chronic heart failure (NYHA class II) despite optimised medical therapy who meet all the following criteria: • Sinus rhythm • LVEF ≤ 30% • QRS duration ≥ 150 ms
Intervention	CRT-D with optimised medical therapy
Comparator	ICD with optimised medical therapy
Outcomes to be assessed	All-cause mortality Sudden cardiac death Hospitalisation for heart failure Patient-related quality of life All adverse events
Healthcare resources to be considered	Cost of device implantation Cost and rate of heart failure hospitalisation Cost and rate of device-related hospitalisation Cost and rate of generator replacement for battery depletion Cost of rate of monitoring Cost and use of pharmaceuticals

Abbreviations: CRT-D, cardiac resynchronisation therapy; ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association
Source: Final decision analytic protocol, 2013

B CLINICAL EVALUATION FOR THE MAIN INDICATION

B.1 DESCRIPTION OF SEARCH STRATEGIES

A full review of the literature was undertaken to all identify randomised trials and systematic reviews that compared the safety and efficacy of CRT-D with ICD in patients with NYHA class II heart failure. A number of approaches were employed to identify relevant studies, including:

- A search of the published literature using the electronic database EMBASE.com, which allows concurrent searching of EMBASE and MEDLINE
- A search of the Cochrane Library and other health technology assessment websites
- A search of clinical trial registries, including the Australian and New Zealand Clinical Trials Registry, the US National Institutes of Health clinical trial database (clinicaltrials.gov), and the European Union Clinical Trials Register
- A search of the Sponsor's databases for published and unpublished trial reports

The search strategies used to identify relevant citations are shown in **Table B-1**. To ensure that all relevant studies were identified, the electronic database searches were not limited by article type, publication date or publication language. The reference lists of relevant articles were also manually reviewed.

Table B-1 Search strategies used to identify direct comparative randomised trials

Database	Search terms		Citations retrieved	Final number of citations, excluding duplicates
EMBASE.com (includes Medline and EMBASE 1966 to present) *(searched on 30 Apr 2013)*	#1	'biventricular pacing':ab,ti OR (cardiac:ab,ti OR ventricular:ab,ti AND (resynchronisation:ab,ti OR resynchronization:ab,ti OR synchronisation:ab,ti OR synchronization:ab,ti)) OR crt:ab,ti	16,975	889
	#2	defibrillat*:ab,ti OR icd:ab,ti	45,770	
	#3	crtd:ab,ti OR 'crt d':ab,ti	1109	
	#4	#1 AND #2	2397	
	#5	#3 OR #4	2755	
	#6	'comparative study'/exp OR 'comparative study' OR 'clinical trial'/exp OR 'clinical trial' OR 'randomized controlled trial'/exp OR 'randomized controlled trial' OR 'randomization'/exp OR 'randomization' OR 'single blind procedure'/exp OR 'single blind procedure' OR 'double blind procedure'/exp OR 'double blind procedure' OR 'triple blind procedure'/exp OR 'triple blind procedure' OR 'crossover procedure'/exp OR 'crossover procedure' OR 'placebo'/exp OR 'placebo' OR placebo* OR random* OR rct OR 'single blind' OR 'single blinded' OR 'double blind' OR 'double blinded' OR 'treble blind' OR 'treble blinded' OR 'triple blind' OR 'triple blinded' OR 'prospective study'/exp OR 'prospective study'	2,742,012	
	#7	'meta analysis'/exp OR 'meta analysis' OR 'systematic review'/exp OR 'systematic review' OR 'pooled analysis' OR ('review'/exp OR 'review' AND (systemat* OR pool*))	199,535	
	#8	#6 OR #7	2,833,878	
	#9	#5 AND #8	890	

Database	Search terms		Citations retrieved	Final number of citations, excluding duplicates
Cochrane Library • Cochrane reviews • Other reviews • Central register of controlled trials • HTA database *(searched on 30 Apr 2013)*	#1	MeSH descriptor: [Cardiac Resynchronization Therapy] explode all trees	68	60
	#2	"biventricular pacing" OR ((cardiac or ventricular) and (resynchronisation OR resynchronization or synchronisation OR synchronization))	439	
	#3	#1 OR #2	439	
	#4	MeSH descriptor: [Defibrillators] explode all trees	813	
	#5	defibrillat*	1429	
	#6	#4 OR #5	1429	
	#7	#3 AND #6	166	
Total citations identified from publication databases				949
Australia and New Zealand Clinical Trials Registry *(searched on 30 Apr 2013)*	#1	cardiac resynchronization	15	34
	#2	defibrillator	21	
Clinicaltrials.gov (*searched on 30 Apr 2013*)	#1	"crt-d" OR "crt d" OR ("cardiac resynchronization" AND defibrillat*)	131	131
European Union Clinical Trials Register (*searched on 30 Apr 2013*)	#1	"crt-d" OR "crt d" OR ("cardiac resynchronization" AND defibrillat*)	5	5
Total citations identified from clinical trial registries				170
Clinical trial reports identified through searches of internal company databases				4
Manually identified citations				2
Total number of citations identified				**1125**

B.2 LISTING OF ALL RELEVANT TRIALS

B.2.1 Identification of relevant publications

All of the identified citations were reviewed based on information in the publication title and, where available, the abstract. Publications deemed to be relevant were retrieved and reviewed in full text before a final decision was made on their inclusion or exclusion for the current review. At both stages of consideration, predefined exclusion criteria were used to identify RCTs and systematic reviews that compared the safety and efficacy of CRT-D with ICD in patients with NYHA class II heart failure. Publications were excluded if they did not report the results of an RCT or systematic review; if they did not include patients with NYHA class II heart failure; and if they did not directly compare the safety and efficacy of CRT-D with ICD.

Table B-2 summarises the application of the exclusion criteria to the identified citations. Most citations were excluded after title/abstract review, for being the wrong study type or evaluating the wrong intervention. Fourteen publications were excluded after full text review as they were systematic reviews or meta-analyses that did not compare the safety or efficacy of CRT-D with ICD in patients with NYHA class II heart failure. A full list of the excluded citations, with reasons for exclusion, is provided in **Appendix E**.

Table B-2 Identification of publications relating to direct comparative randomised trials

	Publication databases[a]	Clinical trial registries[b]	Internal company databases	Manual search
Total number of citations identified	**949**	**170**	**4**	**2**
Number of citations excluded after title/abstract review:				
• Not a randomised trial or systematic review	740	60	-	-
• Does not include patients with NYHA II heart failure	45	35	-	-
• Does not compare CRT-D with ICD	105	70	-	-
Total number of citations excluded after title/abstract review	890	165	-	-
Number of citations reviewed in full text	**59**	**5[c]**	**4**	**2**
Number of citations excluded after full text review:				
• Not a randomised trial or systematic review	-	-	-	-
• Does not include patients with NYHA II heart failure	14[d]	-	-	-
• Does not compare CRT-D with ICD	-	-	-	-
Total number of citations excluded after full text review	14	-	-	-
Total number of included publications	**45**	**-**	**4**	**2**
Publications associated with direct comparative trials	36	-	4	2
Systematic reviews	9	-	-	-

a EMBASE.com (includes MEDLINE and EMBASE) and the Cochrane Library
b Clinicaltrials.gov, European Union Clinical Trials Register, Australia New Zealand Clinical Trials Registry
c The clinical trial registry searches identified five references to clinical trials that had already been identified
d These were systematic reviews or meta-analyses that did not report results for patients with NYHA class II heart failure

In total, the literature search described above identified 46 publications that reported the results of five RCTs which compared CRT-D with ICD in patients with NYHA class II heart failure:

- The Resynchronization–Defibrillation for Ambulatory Heart Failure Trial (RAFT)
- The Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT)
- The Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction trial (REVERSE)
- The Multicenter InSync ICD Randomized Clinical Evaluation II (MIRACLE ICD II)
- A trial published by Higgins et al (2003), referred to as the CONTAK-CD trial

Nine of these publications were systematic reviews that included that included an assessment of CRT-D versus ICD in patients with NYHA class II heart failure. No additional trials were identified through a review of these studies. For completeness, the characteristics and results of the identified systematic reviews have been summarised in **Appendix C.**

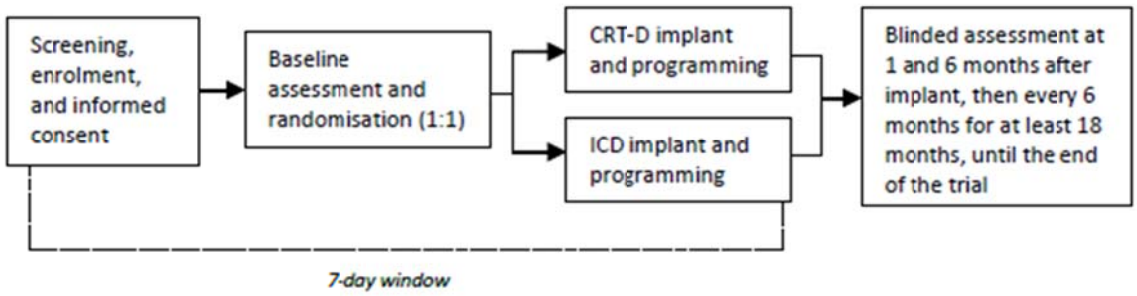
B.2.2 Pivotal evidence for the main clinical evaluation

The RAFT and MADIT-CRT trials directly compared the safety and efficacy of the CRT-D implantation (the proposed medical service) with ICD implantation (the main comparator). These trials provide pivotal evidence for the main clinical evaluation of CRT-D versus ICD in patients with NYHA class II heart failure. A copy of the full clinical study report for each trial is provided for reference in **Attachment 1** and **Attachment 2.**

RAFT

The RAFT trial was a parallel group, randomised, double blind controlled study designed to assess whether the addition of CRT to an ICD and optimised medical therapy would reduce mortality and the rate of hospitalisation for heart failure, compared with an ICD and optimised medical therapy alone. A total of 1798 patients with either NYHA class II or III heart failure were enrolled at 34 centres in Canada, Europe, Australia, and Turkey. Eligible participants were randomised in a 1:1 ratio to undergo either CRT-D or ICD implantation, and were followed for a mean follow-up duration of 40 (standard deviation [SD], 20) months after implant. The primary outcome was defined as death from any cause or hospitalisation for heart failure (Tang et al 2010[77]).

Figure B-1 Simplified schematic of RAFT study design



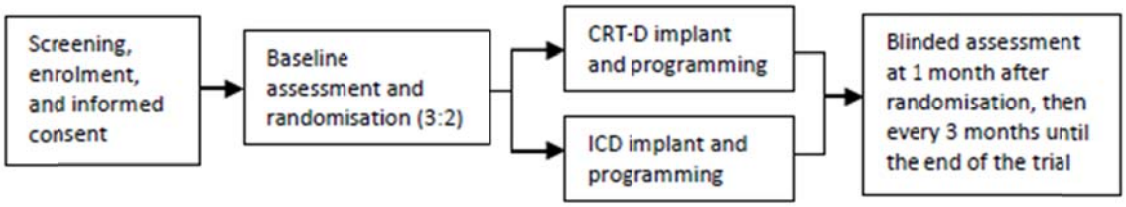
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2009)[76], Tang et al (2010)[77]

It should be noted that the protocol for the RAFT trial was amended partway through the investigation after a different clinical trial (Cleland et al 2005[25]) demonstrated that CRT-P was associated with significant morbidity and mortality benefits in patients with NYHA class III heart failure. Only patients with NYHA class II heart failure were enrolled in this study after February 2006.

MADIT-CRT

The MADIT-CRT trial was designed to determine whether prophylactic CRT in combination with an ICD would reduce the risk of death or non-fatal heart failure events in patients with mild cardiac symptoms, compared with ICD alone. A total of 1820 patients with NYHA class I or II heart failure were enrolled at 110 centres in the US, Europe and Canada. Eligible participants were randomly assigned in a 3:2 ratio to undergo either CRT-D or ICD implantation. The primary outcome was defined as death from any cause or a non-fatal heart failure event, whichever came first (Moss et al 2009[58]). Efficacy and safety boundaries were predefined for monitoring purposes. After a mean follow-up duration of 29 months, an independent data and safety monitoring board determined that the trial had met its primary effectiveness endpoint and showed superiority of CRT-D as compared to ICD. Data continued to be collected for six months after this time point, meaning that the overall mean follow-up duration was 34.3 (SD, 12.2) months (MADIT-CRT CSR).

Figure B-2 Simplified schematic of MADIT-CRT study design



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Moss et al (2005)[57], Moss et al (2009)[58]

B.2.3 Supportive evidence

The REVERSE and MIRACLE ICD II trials did not directly compare the safety and efficacy of the CRT-D implantation (the proposed medical service) with ICD implantation (the main comparator). Instead, each of these trials was designed to compare clinical outcomes occurring in patients who received an active CRT-D implant (CRT-ON), versus patients who received a CRT-D implant programmed to function as an ICD (CRT-OFF). Participants who received a successful CRT-D implant and were included in the randomised phase of each of these studies would have received a left ventricular lead prior to randomisation. Because this lead would not be placed during ICD implantation in clinical practice, the surgical procedures performed within these trials are not representative of the medical services that constitute the main comparator for this application. These trials have therefore been presented as supportive evidence. A copy of the primary publication relating to each study is included in the supportive documentation.

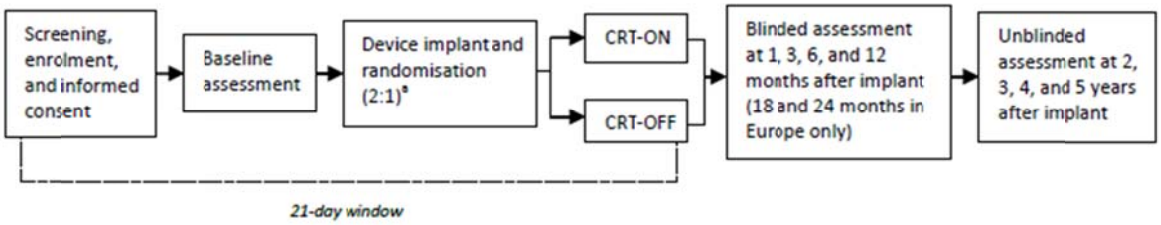
REVERSE

The REVERSE trial was designed to determine whether biventricular pacing limited the progression of heart failure in subject clinical status as compared to optimised medical therapy alone in patients with NYHA class I or II heart failure. A total of 684 participants were enrolled at 73 centres located in the US, Canada and Europe. Participants were screened for eligibility and implanted with a CRT-D (83.3%) or CRT-P (16.7%) system, in accordance with local clinical practice guidelines. Those with a successful implant were then randomly assigned in a 2:1 fashion to have the CRT function either activated (CRT-ON) or deactivated (CRT-OFF). This trial effectively included four interventions: CRT-D implanted with CRT function on; CRT-D implanted with CRT function off (equivalent to an ICD); CRT-P implanted with CRT function on; and CRT-P implanted with CRT function off (equivalent to optimised medical therapy alone) (Linde et al 2008a[48]).

The primary outcome of the REVERSE trial was defined based on the heart failure clinical composite response system defined by Packer et al (2001)[65], which categorises patients as having “worsened”, “unchanged” or “improved” heart failure based on a combination of outcomes, including death, hospitalisation due to or associated with worsening HF, and Patient’s Global Assessment (PGA) scores. Participants enrolled at study centres located in the US and Canada were unblinded 12 months after device implantation, and those enrolled at study centres located in Europe were unblinded after 24 months. After the end of the blinded follow-up period, active CRT programming was recommended for all participants, and participants were requested to attend yearly follow-up visits for a total follow-up duration of five years (Linde et al 2006[49]; Linde et al 2008a[48]).

The primary publication and clinical study report relating to the REVERSE trial did not stratify study results by the type of device initially implanted. CRT-P systems do not deliver defibrillation therefore patients in the CRT-P instead of an ICD would have an increased and untreated risk for SCD. The inclusion of patients who received a CRT-P in the primary analysis of the REVERSE trial biases means that overall trial results are biased against the CRT-ON treatment group. *Post hoc* analyses investigating this issue are currently underway.

Figure B-3 Simplified schematic of REVERSE study design



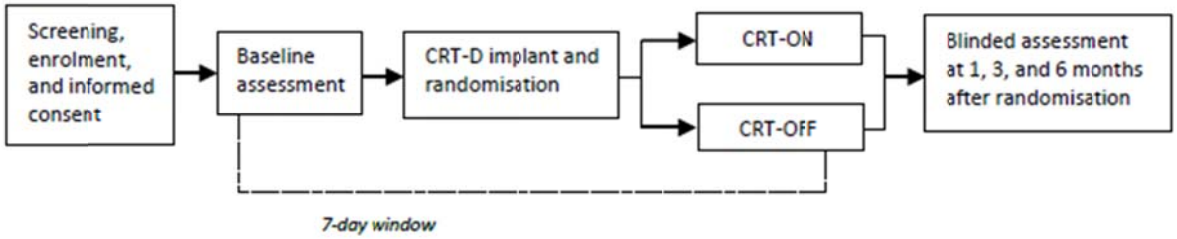
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Linde et al (2006)[49], Linde et al (2008a)[48]

a Eligible participants were implanted with a CRT-D or CRT-P device in accordance with local clinical practice guidelines. In total, 83.3% of participants received a CRT-D and 16.7% received a CRT-P.

MIRACLE ICD II

The MIRACLE ICD II trial examined whether the addition of CRT to an ICD slows disease and improves exercise performance in patients with NYHA class II heart failure. A total of 222 participants were enrolled at 51 centres located in the US and Canada. All participants underwent CRT-D implantation, and those with a successful CRT-D implant were randomly assigned to have the CRT function activated (CRT-ON) or deactivated (CRT-OFF). Follow-up assessments were held at one, three and six months after randomisation. The primary outcome of this trial was defined as the change in peak VO_2 from baseline to six months after randomisation (Abraham et al 2004[1]).

Figure B-4 Simplified schematic of MIRACLE ICD II study design



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Abraham et al (2004)[1]

B.2.4 Excluded trials

The CONTAK-CD trial assessed the safety and effectiveness of CRT when combined with an ICD in patients with NYHA class II, III or IV heart failure. All eligible participants were required to undergo CRT-D implantation, and those with a successful implant were randomly assigned to have the CRT function activated 30 days after implantation (CRT-ON) or deactivated (CRT-OFF). The trial was originally designed as a crossover study with two three-month observation periods however the crossover stage was removed partway through the investigation due to regulatory concerns about the insufficient length of follow-up. Instead of crossing over, the treatment groups were followed in parallel for six months (Higgins et al 2003[41]). As noted by Abraham et al (2004)[1], the CONTAK-CD trial is limited by the fact that a major change in design was implemented during the investigation, by the instability of patients' NYHA classes and medical therapy at enrolment, and by inherent difficulties in subgroup analysis. This trial has been excluded from the evaluation of whether CRT-D is safe and effective in the proposed MBS population. This approach is consistent with the other systematic reviews evaluating the safety and efficacy of CRT-D versus ICD (e.g. Wells et al 2011[81]).

Table B-3 Master list of trials and publications relevant to this assessment report

Study ID	Citation details
Pivotal trials	
RAFT[38,39,55,76,77]	Primary publication Tang et al (2010) Cardiac resynchronization therapy for mild to moderate heart failure. *New England Journal of Medicine* 363:2385-2395. Clinical study report Medtronic (2011) RAFT - Clinical report in support of pre-market approval. 18 January 2011. Protocol Tang et al (2009) Resynchronization/defibrillation for ambulatory heart failure trial: Rationale and trial design. *Current Opinion in Cardiology* 24:1-8. Secondary publications Healey et al (2012a) A randomized controlled pilot study comparing ICD implantation with and without intraoperative defibrillation testing in patients with heart failure and severe left ventricular dysfunction: A sub-study of the RAFT trial. *Journal of Cardiovascular Electrophysiology* 23:1313-1316. Healey et al (2012b) Cardiac resynchronization therapy in patients with permanent atrial fibrillation: Results from the Resynchronization for Ambulatory Heart Failure Trial (RAFT). *Circulation: Heart Failure* 5:566-570.
MADIT-CRT[7,12-14,17,19-21,33-35,42,44-46,53,57,63,66,71,74,75,80,86]	Primary publication Moss et al (2009) Cardiac resynchronization therapy for the prevention of heart failure events. *New England Journal of Medicine* 361:1329-1338. Clinical study report Boston Scientific (2011) Clinical summary: MADIT-CRT. Protocol Moss et al (2005) Multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT): Design and clinical protocol. *Annals of Noninvasive Electrocardiology* 10:34-43. Secondary publications Arshad et al (2011) Cardiac resynchronization therapy is more effective in women than in men: The MADIT-CRT (multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy) trial. *Journal of the American College of Cardiology* 57:813-820. Barsheshet et al (2011a) Reverse remodeling and the risk of ventricular tachyarrhythmias in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 57:2416-2423. Barsheshet et al (2011b) Response to preventive cardiac resynchronization therapy in patients with ischaemic and non-ischaemic cardiomyopathy in MADIT-CRT. *European Heart Journal* 32:1622-1630. Barsheshet et al (2011c) Time-dependent benefit of preventive cardiac resynchronization therapy after myocardial infarction. *European Heart Journal* 32:1614-1621. Brenyo et al (2011) Cardiac resynchronization therapy reduces left atrial volume and the risk of atrial tachyarrhythmias in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 58:1682-1689. Buber et al (2011) Clinical course and outcome of patients enrolled in US and non-US centres in MADIT-CRT. *European Heart Journal* 32:2697-2704. Buber et al (2012) Reduction in life-threatening ventricular tachyarrhythmias in statin-treated patients with nonischemic cardiomyopathy enrolled in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 60:749-755. Goldenberg et al (2010) Relation between renal function and response to cardiac resynchronization therapy in Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT). *Heart Rhythm* 7:1777-1782. Goldenberg et al (2011a) Reduction of the risk of recurring heart failure events with cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with

Study ID	Citation details
	Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 58:729-737. Hsu et al (2012) Predictors of super-response to cardiac resynchronization therapy and associated improvement in clinical outcome: The MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) study. *Journal of the American College of Cardiology* 59:2366-2373.Knappe et al (2011) Dyssynchrony, contractile function, and response to cardiac resynchronization therapy. *Circulation: Heart Failure* 4:433-440. Kutyifa et al (2013) Left ventricular lead location and the risk of ventricular arrhythmias in the MADIT-CRT trial. *European Heart Journal* 34:184-190. Kutyifa et al ((2013) Dyssynchrony and the risk of ventricular arrhythmias. *JACC: Cardiovascular Imaging* 6:432-444. Kutyifa et al (2013) The influence of left ventricular ejection fraction on the effectiveness of cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 61:936-944. Martin et al (2011) Cardiac resynchronization therapy reduces the risk of cardiac events in patients with diabetes enrolled in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). *Circulation: Heart Failure* 4:332-338. Noyes K, Veazie P, Hall WJ, Zhao H, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2013) Cost-effectiveness of cardiac resynchronization therapy in the MADIT-CRT trial. *Journal of Cardiovascular Electrophysiology* 24:66-74. Pouleur et al (2011) Relationship between improvement in left ventricular dyssynchrony and contractile function and clinical outcome with cardiac resynchronization therapy: The MADIT-CRT trial. *European Heart Journal* 32:1720-1729 Ruwald et al (2013) Effect of metoprolol versus carvedilol on outcomes in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 61:1518-1526. Singh et al (2011) Left ventricular lead position and clinical outcome in the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT) trial. *Circulation* 123:1159-1166. Solomon et al (2010) Effect of cardiac resynchronization therapy on reverse remodeling and relation to outcome: Multicenter automatic defibrillator implantation trial: Cardiac resynchronization therapy. *Circulation* 122:985-992. Veazie et al (2012) Cardiac resynchronization and quality of life in patients with minimally symptomatic heart failure. Journal of the American College of Cardiology 60:1940-1944. Zareba et al (2011) Effectiveness of Cardiac Resynchronization Therapy by QRS Morphology in the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT). *Circulation* 123:1061-1072.
Supportive trials	
REVERSE[27,32,48-50]	Primary publication Linde et al (2008a) Randomized Trial of Cardiac Resynchronization in Mildly Symptomatic Heart Failure Patients and in Asymptomatic Patients With Left Ventricular Dysfunction and Previous Heart Failure Symptoms. *Journal of the American College of Cardiology* 52:1834-1843. Clinical study report Medtronic (2012) REVERSE Final Report. 30 March 2012. Protocol Linde et al (2006) Rationale and design of a randomized controlled trial to assess the safety and efficacy of cardiac resynchronization therapy in patients with asymptomatic left ventricular dysfunction with previous symptoms or mild heart failure—the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) study. *American Heart Journal* 151:288-94. Secondary publications Daubert et al (2009) Prevention of Disease Progression by Cardiac Resynchronization Therapy in

Study ID	Citation details
	Patients With Asymptomatic or Mildly Symptomatic Left Ventricular Dysfunction. Insights From the European Cohort of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) Trial. *Journal of the American College of Cardiology* 54:1837-1846. Gold et al (2011) The impact of cardiac resynchronization therapy on the incidence of ventricular arrhythmias in mild heart failure. *Heart Rhythm* 8:679-684.Linde et al (2010) Cardiac resynchronization therapy in asymptomatic or mildly symptomatic heart failure patients in relation to etiology: Results from the reverse (REsynchronization reVErses Remodeling in Systolic Left vEntricular Dysfunction) study. *Journal of the American College of Cardiology* 56:1826-1831. Linde et al (2008b) Baseline characteristics of patients randomized in the Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) study. *Congestive Heart Failure* 14: 66-74.
MIRACLE ICD II[1]	Primary publication Abraham et al (2004) Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. *Circulation* 110:2864-2868. Clinical study report Medtronic (2003). Medtronic® model 272 INSYNC ICD® cardiac resynchronization system: Final Clinical Report. 12 February 2003.
Relevant systematic reviews[a]	
Adabag (2011)[2]	Adabag et al (2011) Cardiac resynchronization therapy in patients with minimal heart failure: A systematic review and meta-analysis. *Journal of the American College of Cardiology* 58:935-941.
Al-Majed (2011)[3]	Al-Majed et al (2011) Meta-analysis: cardiac resynchronization therapy for patients with less symptomatic heart failure. *Annals of Internal Medicine* 154:401-412.
Bertoldi (2011)[15]	Bertoldi et al (2011) Mortality reduction of cardiac resynchronization and implantable cardioverter-defibrillator therapy in heart failure: An updated meta-analysis. Does recent evidence change the standard of care? *Journal of Cardiac Failure* 17:860-866.
Chen (2012)[24]	Chen et al (2012) Effect of cardiac resynchronization therapy and implantable cardioverter-defibrillator on quality of life in patients with heart failure: A meta-analysis. *Europace* 14:1602-1607.
Lubitz (2010)[52]	Lubitz et al (2010) Effectiveness of cardiac resynchronization therapy in mild congestive heart failure: systematic review and meta-analysis of randomized trials. *European Journal of Heart Failure* 12:360-366.
Santangeli (2011)[73]	Santangeli et al (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis. *Journal of Interventional Cardiac Electrophysiology* 32:125-135.
Tu (2011)[78]	Tu et al (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis of randomized controlled trials. *Cardiovascular Drugs and Therapy* 25:331-340.
Wells (2011)[81]	Wells et al (2011) Cardiac resynchronization therapy: A meta-analysis of randomized controlled trials. *CMAJ* 183:421-429.
Zareba (2010)[85]	Zareba (2010) Comparison of clinical trials evaluating cardiac resynchronization therapy in mild to moderate heart failure. *Cardiology Journal* 17:543-548.

a The characteristics and results of the identified systematic reviews and meta-analyses are summarised in **Appendix C**.

Table B-4 Comparative summary of trial characteristics and results

Study ID	Design characteristics	Summary of main population characteristics	Compared interventions (N)	Summary of results	
				Primary outcomes	Secondary outcomes
Pivotal trials					
RAFT	R, DB, MC, PG	Patients with NYHA class II or III heart failure despite OMT, with: • Sinus rhythm or permanent atrial fibrillation or flutter with a controlled ventricular rate • LVEF ≤ 30% • QRS duration of ≥ 120 ms or paced QRS duration of ≥ 200 ms	CRT-D implant (N = 894) versus ICD implant (N = 904)	ITT population • Death from any cause or hospitalisation for heart failure occurred in 33.2% of patients in the CRT-D arm, versus 40.3% of patients in the ICD arm, over a mean follow-up duration of 40 (SD, 20) months • RR for death from any cause or hospitalisation for heart failure: 0.83 (95% CI, 0.73 to 0.93), in favour of CRT-D, over a mean follow-up duration of 40 (SD, 20) months NYHA class II subgroup • Death from any cause or hospitalisation for heart failure occurred in 27.3% of patients in the CRT-D arm, versus 34.7% of patients in the ICD arm, over a mean follow-up duration of 40 (SD, 20) months • RR for death from any cause or hospitalisation for heart failure: 0.71 (95% CI, 0.56 to 0.88), in favour of CRT-D	ITT population • All-cause mortality: 20.8% for CRT-D versus 26.1% for ICD (RR, 0.80; 95% CI, 0.67 to 0.94) • Cardiovascular mortality: 14.5% for CRT-D versus 17.9% for ICD (RR, 0.81; 95% CI, 0.66 to 1.0) • Hospitalisation for heart failure: 19.5% for CRT-D versus 26.1% for ICD (RR, 0.75; 95% CI, 0.63 to 0.89) • Device-related hospitalisation: 20.0% for CRT-D versus 12.2% for ICD (RR, 1.65; 95% CI, 1.32 to 2.05) • AEs occurring within 30 days of implant: 13.3% for CRT-D versus 6.8% for ICD NYHA class II subgroup • All-cause mortality: 15.5% for CRT-D versus 21.2% for ICD (RR, 0.79; 95% CI, 0.67 to 0.92) • Cardiovascular mortality: 10.5% for CRT-D versus 13.7% for ICD (RR, 0.76; 95% CI, 0.58 to 0.92) • Hospitalisation for heart failure: 16.2% for CRT-D versus 21.8% for ICD (RR, 0.75; 95% CI, 0.60 to 0.93)

Study ID	Design characteristics	Summary of main population characteristics	Compared interventions (N)	Summary of results	
				Primary outcomes	**Secondary outcomes**
MADIT-CRT	R, DB, MC, PG	Patients with ischaemic cardiomyopathy (NYHA class I or II) or non-ischaemic cardiomyopathy (NYHA class II), with: • Sinus rhythm • LVEF ≤ 30% • QRS duration of ≥ 130 ms	CRT-D implant (N = 1089) versus ICD implant (N = 731)	ITT population • Death from any cause or a non-fatal heart failure event occurred in 19.1% of patients in the CRT-D arm, versus 28.4% of patients in the ICD arm, over a mean follow-up duration of 34.3 (SD, 12.2) months • RR for death from any cause or a non-fatal heart failure event: 0.0.67 (95% CI, 0.57 to 0.79), in favour of CRT-D	ITT population • All-cause mortality: 8.4% for CRT-D versus 9.3% for ICD (RR, .0.91; 95% CI, 0.57 to 0.79) • Cardiac mortality: 4.2% for CRT-D versus 5.9% for ICD • Heart failure event: 14.8% for CRT-D versus 25.4% for ICD (RR, 0.58; 95% CI, 0.48 to 0.70) • Device-related hospitalisation: 20.0% for CRT-D versus 12.2% for ICD (RR, 1.65; 95% CI, 1.32 to 2.05) • SRCs occurring within 30 days of implant: 13.3% across both treatment groups
Supportive evidence					
REVERSE	R, DB, MC, PG	Patients with NYHA class I or II HF despite OMT, with: • Sinus rhythm • LVEF ≤ 40% • QRS duration of ≥ 120 ms • LV end diastolic diameter ≥ 55 mm	CRT-D or CRT-P implant with CRT-ON (N = 419) versus CRT-D or CRT-P implant with CRT-OFF (N = 191) In total, 83.3% of participants received a CRT-D and 16.7% a CRT-P	ITT population • At 12 months after randomisation, 16.0% of participants in the CRT-ON group were classified as having a worsened clinical composite response, compared with 21.5% of participants in the CRT-OFF group • RR for worsened clinical composite response: 0.74 (95% CI, 0.53 to 1.06), in favour of CRT-D but not statistically significant	ITT population • All-cause mortality: 2.1% for CRT-ON versus 1.6% for CRT-OFF (RR, 1.37; 95% CI, 0.37 to 4.99) • Hospitalisation due to or associated with worsening heart failure: 2.9% for CRT-ON versus 7.3% for CRT-OFF (RR, 0.39; 95% CI, 0.18 to 0.83) • SRCs occurring during or just before implantation: 4.0% across both treatment groups

Study ID	Design characteristics	Summary of main population characteristics	Compared interventions (N)	Summary of results	
				Primary outcomes	**Secondary outcomes**
				European cohort • At 24 months after randomisation, 18.9% of participants in the CRT-ON group were classified as having a worsened clinical composite response, compared with 34.1% of participants in the CRT-OFF group • RR for worsened clinical composite response: 0.55 (95% CI, 0.36 to 0.85), in favour of CRT-OFF	European cohort • All-cause mortality: 2.2% for CRT-ON versus 8.5% for CRT-OFF (RR, 0.26; 95% CI, 0.0.08 to 0.86) • Hospitalisation due to or associated with worsening heart failure: 6.7% for CRT-ON versus 14.6% for CRT-OFF (RR, 0.46; 95% CI, 0.21 to 0.97) • SRCs occurring during or just before implantation: 4.0% across both treatment groups
MIRACLE ICD II	R, DB, MC, PG	Patients with NYHA class II HF despite OMT, with: • LVEF ≤ 35% • QRS duration of ≥ 130 ms • LV end diastolic diameter ≥ 55 mm	CRT-D implant with CRT-ON (N = 85) versus CRT-D implant with CRT-OFF (N = 101)	ITT population At 6 months after randomisation, mean change in peak VO_2 from baseline was 0.5 mL/kg/min^{-1} (SD 3.2) for CRT-ON versus 0.2 mL/kg/min^{-1} (SD 3.2) for CRT-OFF, with no significant difference between treatment arms (P=0.87)	ITT population • All-cause mortality: 2.4% for CRT-ON versus 2.0% for CRT-OFF • Worsened overall clinical status: 20.0% for CRT-ON versus 30.7% for CRT-OFF • At six months after randomisation, participants in the CRT-ON group had improved exercise time and 6 minute walk distance, but these results were not statistically different from the CRT-OFF group • Echocardiographic assessments showed that participants in the CRT-ON group had significantly reduced left ventricular end diastolic and end systolic volumes and a significantly improved LVEF • Peri-operative complications: 22% across both treatment groups

Study ID	Design characteristics	Summary of main population characteristics	Compared interventions (N)	Summary of results	
				Primary outcomes	Secondary outcomes
Excluded trials					
CONTAK-CD	R, DB, MC, CO	Patients with NYHA class II, III or IV HF, with: • LVEF ≤ 35% • QRS duration of ≥ 120 ms	CRT-D implant with CRT-ON (N = 245) versus CRT-D implant with CRT-OFF (N = 245)	ITT population • Heart failure progression events occurred in 32.2% of patients in the CRT-ON group, versus 38.4% of patients in the CRT-OFF group, over the six month trial duration (not statistically significant)	ITT population • Mean change in peak VO_2 from baseline: 0.8 ml/kg/min versus 0.0 ml/kg/min (P=0.03), in favour of CRT-ON • Mean change in 6MWD 35 m versus 15m (P=0.043), in favour of CRT-ON • No differences between treatment groups in mean change in NYHA class or mean change in NYHA score

Abbreviations: 6MWD, 6-minute walk distance; CI, confidence interval; CO, crossover; CRT-D, cardiac resynchronisation device capable of defibrillation; CRT-ON, cardiac resynchronisation activated; CRT-OFF, cardiac resynchronisation not activated; DB, double blind; ICD, implantable cardioverter-defibrillator; ITT, intention-to-treat; MC, multicentre; NYHA, New York Heart Association; PG, parallel group; R, randomised; RR, relative risk; SRC, system-related complication

Source: Tang et al (2009)[76], Tang et al (2010)[77], Moss et al (2005)[57], Moss et al (2009)[58], Linde et al (2006)[49], Linde et al (2008a)[48], Abraham et al (2004)[1], Higgins et al (2003)[41]

B.3 ASSESSMENT OF THE MEASURES TAKEN TO MINIMISE BIAS

Table B-5 summarises the measures taken to minimise bias in the each of the identified studies. Due to the surgical nature of CRT-D and ICD implantation, it is not possible or appropriate to blind the medical staff responsible for device insertion, programming or interrogation. Each of the included studies, however, used specific methods to blind participants, investigators and outcome assessors to treatment assignment wherever possible. In all of the identified trials, the randomisation sequence was concealed to minimise the risk of selection bias and the primary analyses were conducted based on an intention-to-treat (ITT) approach.

Table B-5 Summary of measures used to minimise bias in the included direct comparative randomised trials

Study ID	Concealment of randomisation	Blinding			Basis of analysis[a]
		Participants	Investigators	Outcome assessors	
Pivotal trials					
RAFT	Central telephone randomisation service	Yes	Yes	Yes	ITT
MADIT-CRT	Central web or telephone randomisation service	Yes	Yes	Yes[b]	ITT
Supportive trials					
REVERSE	Sealed envelopes	Yes	Yes	Yes	ITT
MIRACLE ICD II	Sealed envelopes	Yes	Yes	Yes	ITT

Abbreviations: ITT, intention-to-treat, PP, per-protocol

Source: Tang et al (2009)[76], Tang et al (2010)[77], Moss et al (2005)[57], Moss et al (2009)[58], Linde et al (2006)[49], Linde et al (2008a)[48], Abraham et al (2004)[1]

a ITT population includes all patients who are allocated to a study therapy, regardless of whether or not they actually received the therapy, and regardless of whether they changed therapy during the trial.

b In the MADIT-CRT trial, heart failure events were initially reported by physicians who were aware of the treatment assignments, but were adjudicated by a blinded committee.

B.3.1 Randomisation

RAFT

Eligible participants in the RAFT trial were randomly assigned in a 1:1 ratio to undergo either CRT-D or ICD implantation. Randomisation was implemented using a central telephone-based service, and randomisation schedules were stratified by centre, presence of atrial fibrillation, and type of ICD indicated (i.e. single-chamber or dual-chamber ICD) (Tang et al 2010[77]).

MADIT-CRT

Eligible participants in the MADIT-CRT trial were randomly assigned in a 3:2 ratio to undergo either CRT-D or ICD implantation. Treatment allocations were made at a central coordination and data centre, and were transmitted to the enrolling clinical centre by logging on to a Web-based automated program or by telephone, after patients had undergone baseline evaluations and performed informed consent. Randomisation was stratified by study centre and type of cardiomyopathy (i.e. ischaemic or non-ischaemic) and an algorithm was used to ensure balance in each stratum (Moss et al 2005[57]).

REVERSE

Eligible participants were implanted with a CRT-D or CRT-P device in accordance with local clinical practice guidelines. Those with a successful implant were then randomly assigned in a 2:1 ratio to have the CRT function activated (CRT-ON) or deactivated (CRT-OFF) (Linde et al 2008a[48]). The randomisation sequence was concealed using a sequential envelope-based system, and randomisation schedules were stratified by centre and the type of device implanted (i.e. CRT-D or CRT-P) (Linde et al 2008a[48]).

MIRACLE ICD II

Eligible participants with a successful CRT-D implant were randomly assigned in a 1:1 ratio to have the CRT function activated (CRT-ON) or deactivated (CRT-OFF). The randomisation sequence was concealed using a sequential envelope-based system, and randomisation schedules were stratified by study centre (Abraham et al 2004[1]).

B.3.2 Blinding

RAFT

Blinding was achieved by using similar surgical procedures for CRT-D and ICD implantation and performing implantation while participants were well-sedated or under general anaesthesia. The implanted devices were identical in size and shape. Although different electrode leads were inserted for participants in each treatment group, it was determined that participants would have no way of knowing which treatment had been allocated by touch or feel (Tang et al 2009[76]). In order to maintain the blinding process, participants were required to visit two separate clinics at each follow-up assessment. At each heart failure clinic visit, a blinded medical team was responsible for heart failure follow-up assessments, medication adjustments and assessment of subjective outcome measures such as cause of death or hospitalisation, changes in NYHA class, and assessment of health-related quality of life. At each device management clinic, an unblinded medical team was responsible for ECG and device interrogation assessments. ECG and device interrogation records were concealed from the blinded team for the duration of the trial (Tang et al 2009[76]; Tang et al 2010[77]).

MADIT-CRT

Participants were blinded for the entire study duration. Clinical outcomes, deaths and heart failure events were documented by physicians who were aware of the treatment assignments, but were adjudicated by independent committees blinded to treatment group. These committees made decisions on whether events were heart failure or device-related based on a review of clinical data from hospital or outpatient subject records (Moss et al 2005[57]; Moss et al 2009[58]).

REVERSE

Participants were implanted with CRT or CRT-D devices in accordance with local clinical practice. Unblinded electrophysiology personnel were responsible for device programming, device interrogation and follow-up ECG and echocardiography assessments. The echocardiography recordings were evaluated by core labs that were not informed of treatments assigned. A blinded team of medical staff were responsible for managing heart failure, conducting physical examinations, administering quality of life questionnaires and assessing NYHA class. Investigators were asked to report all adverse events, which were classified as being heart failure-related or device-related by an independent Adverse Event Advisory/Endpoint Committee blinded to treatment modality. An unblinded independent Data Monitoring Committee consisting of three physician-scientists and a

statistician reviewed accumulating adverse events, hospitalisation, and mortality data to monitor for safety issues. In the US and Canada, treatment allocations were revealed 12 months after device implantation. In Europe, blinding was maintained for a total of 24 months (Linde et al 2006[49]; Linde et al 2008a[48]).

MIRACLE ICD II

Participants in both treatment groups were implanted with identical CRT-D devices. Only the electrophysiologist responsible for device programming was aware of whether the CRT function had been activated or deactivated, and this person was responsible for performing all tests that could reveal the identity of the assigned mode. Blinding was maintained for six months after device implantation. After the final blinded follow-up visit, treatment allocations could be revealed, and CRT could be activated in patients initially assigned to receive ICD therapy alone (Abraham et al 2004[1]).

B.3.3 Adequacy of follow-up

Table B-6 summarises the flow of participants through each of the identified studies. Only a small number of participants died, discontinued or were lost to follow-up in each study. Some participants switched treatments during the blinded phase of each trial, however all trials assessed results on the basis of the original treatment assignment (ITT).

Table B-6 Flow of participants through the direct comparative randomised trials

Study ID	No. randomised N	Did not receive intervention n (%)	Withdrawal or lost to follow-up n (%)	Analysed n (%)
Pivotal trials				
RAFT				
CRT-D	894	6 (0.7)	10 (1.1)	894 (100)
ICD	904	5 (0.6)	5 (0.6)	904 (100)
MADIT-CRT				
CRT-D	1089	11 (1.0)	44 (4.0)	1089 (100)
ICD	731	19 (2.6)	55 (7.5)	731 (100)
Supportive trials				
REVERSE[a]				
CRT-ON	419	0 (0)	0 (0)	419 (100)
CRT-OFF	191	0 (0)	0 (0)	191 (100)
MIRACLE ICD II[b]				
CRT-ON	85	0 (0)	3 (3.5)	85 (100)
CRT-OFF	101	0 (0)	3 (3.0)	101 (100)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Moss et al (2009)[58], Linde et al (2008a)[48], Abraham et al (2004)[1]

a Participants in the REVERSE trial were randomised after successful CRT-D or CRT implantation. The trial enrolled a total of 684 patients with NYHA class I or II heart failure. Of those, 648 completed a baseline assessment, and 621 were successfully implanted with a CRT-D (83.3%) or CRT-P (16.7%) device. Eleven participants with a successful implant were not randomised for a variety of reasons. In total, 610 implanted patients were included and randomised in this trial.

b Participants in the MIRACLE ICD II trial were randomised after successful CRT-D implantation. The trial initially enrolled 222 patients with NYHA class II heart failure. Of those, 210 patients underwent an implant attempt, and implantation was successful in 191 patients. During the period between implantation and randomisation, one patient died and four had left ventricular lead dislodgements that were not corrected. A total of 186 implanted patients were therefore randomised in this trial.

RAFT

The RAFT trial enrolled a total of 1798 patients with NYHA II or III heart failure. Of the 894 patients randomised to receive CRT-D implantation, 888 (99.3%) underwent device implantation. Reasons for non-implantation included four cases in which the patient died before surgery and two cases in which the patient or physician declined to participate. Left ventricular lead implantation was successful in 841 (94.1%) of participants in the CRT-D group. In 802 cases this was successful during the initial implant attempt and in 39 cases this was successful during a subsequent implant attempt. Of the 904 patients randomised to receive ICD implantation, 899 (99.4%) underwent device implantation. Reasons for non-implantation included four cases in which the patient or physician declined to participate and once case in which there was lack of venous access. A small proportion of participants in the ICD group crossed over to receive cardiac resynchronisation in addition to ICD before the occurrence of a primary outcome event (36 cases, 4.0%), or after hospitalisation for heart failure (60 cases, 6.0%). Fifty-three (6.0%) participants in the CRT-D group did not receive cardiac resynchronisation due to left ventricular lead failure (47 cases) or lead malfunction (6 cases). Ten participants in the CRT-D group and five in the ICD group discontinued early or were lost to follow-up during the trial. Missing data was considered to be missing at random, and was handled using mixed methods repeated measures (MMRM) and multiple imputation techniques (Tang et al 2010[77]).

MADIT-CRT

The MADIT-CRT trial enrolled a total of 1820 patients with NYHA class I or II heart failure. Of the 1089 patients randomised to receive CRT-D implantation, 11 (1.0%) did not undergo device implantation and 82 (7.5%) crossed over to receive ICD implantation because of technical difficulties in positioning the left ventricular electrode lead in the coronary vein. Of the 731 patients randomised to receive ICD implantation, 19 (2.6%) did not undergo device implantation and 91 (12.4%) crossed over to receive a CRT-D device during the trial. Overall, 98.4% of participants received either CRT-D or ICD implantation, and 95.4% of participants received the device to which they had been assigned. A total of 44 (4.0%) participants in the CRT-D group and 55 (7.5%) participants in the ICD group declined to continue participating in the study, were withdrawn by a physician, or were lost to follow-up. Devices were removed during the trial for a variety of reasons in 14 (1.3%) participants in the CRT-D group and in 5 (0.7%) participants in the ICD group. The study was designed to minimise the amount of missing data. Standard data collection procedures were applied and monitoring was performed during the course of the study in order to minimise the amount of missing data. Methods of survival analysis (e.g. Kaplan-Meier methods and log-rank statistics) were used to analyse all available data as appropriate for study endpoints. These standard methods use the maximal amount of information for patients that have not yet experienced an event. All sensitivity analysis results were consistent with the main results suggesting that the endpoint was robust with respect to different assumptions. (Moss et al 2005[57]; Moss et al 2009[58]; MADIT-CRT CSR[17]).

REVERSE

The REVERSE trial enrolled a total of 684 patients with NYHA class I or II heart failure, of whom 648 (94.7%) completed a baseline assessment, and 621 (90.8%) were successfully implanted with a CRT-D or CRT-P device. Eleven of the 621 participants with a successful device implant were not randomised for the following reasons: inclusion criteria not met, complete heart block, atrial arrhythmias, left ventricular lead dislodgment, loss of capture, death, heart failure status, and surgical epicardial left ventricular lead use. The remaining 610 participants were randomly assigned to have the CRT function activated (CRT-ON, n = 419) or deactivated (CRT-OFF, n = 191). No randomised patients discontinued early or were lost to follow-up. Six participants crossed over from the CRT-ON group to the CRT-OFF group due to worsening heart failure, diaphragmatic nerve stimulation, persistent atrial fibrillation or incorrect programming. Fourteen patients crossed over from the CRT-OFF group to the

CRT-ON group due to worsening heart failure, patient unwillingness to remain in the assigned mode and inadvertent erroneous programming. Missing data was handled using the last observation carried forward (LOCF) approach (Linde et al 2008a[48]).

MIRACLE ICD II

The MIRACLE ICD II trial enrolled a total of 222 participants with NYHA class II heart failure, of whom, 191 (90.9%) successfully received a CRT-D device. One participant with a successful CRT-D implant died between surgery and randomisation, and four patients experienced left ventricular lead dislodgements that were not corrected. The remaining 186 implanted participants were randomly assigned to have the CRT function activated (CRT-ON, n = 85) or deactivated (CRT-OFF, n = 101). Of the 85 participants assigned to the CRT-ON group, two died, one was lost to follow-up and two crossed over from active CRT to no CRT because of left ventricular lead dislodgement or diaphragmatic stimulation. Of the 101 participants assigned to the CRT-OFF group, two died, one was lost to follow-up and five crossed over to receive active CRT because of bradycardia, a centre error, or pacemaker dependency after atrioventricular node ablation for atrial flutter. Missing data was handled using the LOCF approach (Abraham et al 2004[1]).

B.4 CHARACTERISTICS OF THE TRIALS

B.4.1 Eligibility criteria

Table B-7 summarises the main inclusion and exclusion criteria for each direct comparative trial presented in this application. These criteria were broadly consistent, with each trial including heart failure patients with a low LVEF and a prolonged QRS duration, despite optimised medical therapy, and excluding those who had experienced recent cardiovascular events, or had heart failure due to valvular disease. Unlike the other trials, RAFT included a subgroup of participants with permanent atrial fibrillation or flutter. This subgroup accounted for 12.7% of the overall RAFT trial population (Tang et al 2010[77]).

Table B-7 Inclusion and exclusion criteria for the direct comparative randomised trials

Criteria	RAFT[a,b]	MADIT-CRT	REVERSE	MIRACLE ICD II
Inclusion criteria				
Patients with chronic heart failure				
• Functional class	II or III	I or II	I or II	II
• Sinus rhythm	-	✓	✓	-
• LVEF	≤ 30%	≤ 30%	≤ 40%	≤ 35%
• QRS duration	≥ 120 ms	≥ 130 ms	≥ 120 ms	≥ 130 ms
• LV end diastolic dimension	-	-	≥ 55 mm	≥ 55 mm
Stable optimised medical therapy	✓	✓	✓	✓
Provided written informed consent	✓	✓	✓	✓
Exclusion criteria				
Chronic or persistent atrial arrhythmia	-	✓	✓	✓
Existing indication for CRT or permanent cardiac pacing	-	✓	✓	✓
Current implanted device:				
• Implanted pacemaker	-	✓	✓	-
• Implanted ICD	✓	✓	✓	-
Limited life expectancy (≤ 6 months or ≤ 12 months)	✓	-	✓	✓

Criteria	RAFT[a,b]	MADIT-CRT	REVERSE	MIRACLE ICD II
Recent cardiovascular event (e.g. unstable angina, acute MI, CABG or percutaneous coronary intervention)	✓	✓	✓	✓
Severe valvular disease or other restrictive, hypertrophic or reversible forms of cardiomyopathy	✓	✓	✓	✓
Prosthetic heart valve	✓	-	✓	-
Heart transplant: • Expected within 12 months • Previous heart transplant	 ✓ -	 - -	 - ✓	 - ✓
Major co-existing condition (e.g. liver dysfunction or severe lung disease)	✓	✓	✓	✓

Abbreviations: CABG, coronary artery bypass graft; CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; LV, left ventricular; LVEF, left ventricular ejection fraction; MI, myocardial infarction
Source: Tang et al 2009[76]; Moss et al 2005[57]; Linde et al 2006[49]; Abraham et al 2004[1]; Young et al 2003[83]
a The RAFT trial initially enrolled patients with NYHA II or III heart failure. Partway through the trial, evidence from a different study (Cleland et al 2005[25]) suggested a mortality benefit for CRT in patients with NYHA class III heart failure who had not undergone implantation of an ICD and there were subsequent changes in clinical practice guidelines. The protocol for the RAFT trial was revised in February 2006 to only include patients in NYHA class II (Tang et al 2010[77]). Patients with an existing pacemaker were included if they satisfied all other inclusion/exclusion criteria and had a paced QRS duration of 200 ms or more (Tang et al 2009[76]).
b The subgroup with permanent atrial fibrillation or flutter was specifically defined as having chronic persistent atrial tachyarrhythmia with resting ventricular heart rate ≤ 60 bpm and 6- minute hall walk heart rate of ≤ 90 bpm OR chronic persistent atrial tachyarrhythmia with resting ventricular heart rate > 60 bpm and 6 Minute Hall Walk Ventricular Heart Rate of > 90 bpm and booked for atrioventricular junction ablation.

B.4.2 Baseline demographic and disease characteristics

Table B-8 summarises the demographic and disease characteristics of participants in the pivotal and supportive trials at baseline. Apart from the fact that the RAFT trial included a subgroup with permanent atrial fibrillation or flutter, there were no major differences between treatment groups or between studies. Over 80% of the population in each trial had NYHA class II heart failure. The mean LVEF in each trial was less than 30% and the mean QRS duration in each trial was greater than 150 ms.

The baseline demographic and disease characteristics of participants in the European cohort of the REVERSE trial are compared with those of the ITT population, and the non-European cohort in **Table B-9**. Participants enrolled at study centres located in Europe were significantly younger than those enrolled at study centres located in the US and Canada, with fewer comorbidities. The European cohort had a lower mean LVEF than the non-European cohort, but a longer intrinsic QRS duration ($P<0.05$ for both comparisons). Fewer participants enrolled in the European cohort received a CRT-D implant (68% versus 95%; $P=0.0001$).

The applicability of information sourced from the pivotal trials to the proposed MBS population is discussed in detail in **Section C.1.**

Table B-8 Baseline characteristics of participants in the direct comparative randomised trials

Characteristic	RAFT		MADIT-CRT		REVERSE		MIRACLE ICD II	
	CRT-D (N = 894)	ICD (N = 904)	CRT-D (N = 1089)	ICD (N = 731)	CRT-ON (N = 419)	CRT-OFF (N = 191)	CRT-ON (N = 85)	CRT-OFF (N = 101)
Age, years – mean (SD)	66.1 (9.3)	66.2 (9.4)	65 (11)	64 (11)	62.9 (10.6)	61.8 (11.6)	63.0 (12.8)	63.1 (12.1)
Male sex – n (%)	758 (84.8)	732 (81.0)	814 (74.7)	553 (75.6)	327 (78.0)	152 (80.0)	75 (88.2)	91 (90.1)
Underlying heart disease – n (%)								
• Ischaemic	614 (68.7)	587 (64.9)	598 (54.9)	401 (54.9)	236 (56.3)	97 (50.7)	47 (55.3)	59 (58.4)
• Non-ischaemic	280 (31.3)	317 (35.1)	491 (45.1)	330 (45.1)	183 (43.7)	94 (49.2)	38 (44.7)	42 (41.6)
NYHA class – n (%)								
• Class I	NA	NA	152 (14.0)	113 (15.5)	75 (17.9)	32 (16.8)	NA	NA
• Class II	708 (79.2)	730 (80.8)	937 (86.0)	618 (84.5)	344 (82.1)	159 (83.2)	85 (100)	101 (100)
• Class III	186 (20.8)	174 (19.2)	NA	NA	NA	NA	NA	NA
LVEF								
• Mean (SD)	22.6 (5.4)	22.6 (5.1)	24 (5)	24 (5)	26.4 (7.1)	26.8 (7.0)	24.4 (6.6)	24.6 (6.7)
• LVEF ≤ 30% - n (%)	894 (100)	904 (100)	1089 (100)	731 (100)	NR	NR	NR	NR
Intrinsic QRS duration								
• QRS duration – mean (SD)	157 (23.6)	158.3 (24.0)	NR	NR	153 (21)	154 (24)	166 (25)	165 (23)
• QRS duration ≥ 150 ms – n, (%)	NR	NR	699 (64.2)	476 (65.1)	NR	NR	NR	NR
QRS morphologic type – n (%)								
• Left bundle branch block	652 (72.9)	643 (71.1)	761/1088 (69.9)	520/729 (71.3)	NR	NR	NR	NR
• Right bundle branch block	68 (7.6)	93 (10.3)	136/1088 (12.5)	92/729 (12.6)	NR	NR	10 (11.8)	21 (20.8)
• NIVCD	106 (11.9)	101 (11.2)	NR	NR	NR	NR	NR	NR
• Ventricular paced	68 (7.6)	67 (7.4)	-	-	-	-	-	-
Atrial rhythm – n (%)								
• Sinus rhythm	780 (87.2)[a]	789 (87.3)[b]	1089 (100)	731 (100)	419 (100)	191 (100)	NR	NR
• Permanent atrial fibrillation or flutter	114 (12.8)	115 (12.7)	NA	NA	NA	NA	NR	NR
CRT-D implanted – n (%)	NA	NA	NA	NA	345 (82.3)	163 (85.3)	NA	NA

Characteristic	RAFT		MADIT-CRT		REVERSE		MIRACLE ICD II	
	CRT-D (N = 894)	ICD (N = 904)	CRT-D (N = 1089)	ICD (N = 731)	CRT-ON (N = 419)	CRT-OFF (N = 191)	CRT-ON (N = 85)	CRT-OFF (N = 101)
Cardiac risk factors – n (%)								
• BMI ≥ 30	NR	NR	385/1072 (35.9)	263/723 (36.4)	NR	NR	NR	NR
• Cigarette smoking	121 (13.5)	127 (14.0)	122/1069 (11.4)	92/717 (12.8)	NR	NR	NR	NR
• Diabetes	293 (32.8)	313 (34.6)	329/1088 (30.2)	223/729 (30.6)	91 (21.7)	46 (24.0)	36/85 (42.4)	41/101 (40.6)
• Hospitalised for heart failure in previous 6 months	238 (894)	223 (904)	NR	NR	NR	NR	NR	NR
• Hypertension	402 (45.0)	397 (43.9)	691/1085 (63.7)	461/730 (63.2)	NR	NR	NR	NR
• Peripheral vascular disease	88 (9.8)	90 (10.0)	NR	NR	NR	NR	NR	NR
• Previous percutaneous coronary intervention	220 (24.6)	208 (23.0)	NR	NR	NR	NR	NR	NR
• Previous CABG	293 (32.8)	313 (34.6)	317/1088 (29.1)	208/730 (28.5)	NR	NR	30/84 (35.7)	30/97 (30.9)
Medication use – n (%)								
• ACE inhibitor	NR	NR	839 (77.0)	563 (77.0)	330 (78.8)	151 (79.1)	83 (97.6)	96 (95.0)
• ARB	NR	NR	227 (20.8)	148 (20.2)	88 (21.0)	39 (20.4)	NR	NR
• ACE inhibitor or ARB	859 (96.1)	878 (97.1)	1039 (95.4)	699 (95.6)	404 (96.4)	186 (97.4)	NR	NR
• Aldosterone antagonist	NR	NR	352 (32.3)	226 (30.9)	NR	NR	NR	NR
• Amiodarone	140 (15.7)	124 (13.7)	78 (7.2)	51 (7.0)	NR	NR	NR	NR
• Aspirin	584 (65.3)	622 (68.8)	NR	NR	NR	NR	NR	NR
• Beta blocker	808 (90.4)	805 (89.0)	1016 (93.3)	681 (93.2)	401 (95.7)	179 (93.7)	54 (63.5)	64 (63.4)
• Calcium-channel blocker	101 (11.3)	83 (9.2)	NR	NR	NR	NR	NR	NR
• Clopidrogel	134 (15.0)	145 (16.0)	NR	NR	NR	NR	NR	NR
• Digitalis or digoxin	301 (33.7)	319 (35.3)	291 (26.7)	177 (24.2)	NR	NR	NR	NR
• Diuretic	757 (84.7)	756 (83.6)	824 (75.7)	533 (72.9)	339 (80.9)	148 (77.5)	74 (87.1)	81 (80.2)
• Lipid-lowering medication	NR	NR	NR	NR	NR	NR	NR	NR
• Spironolactone	372 (41.6)	378 (41.8)	NR	NR	NR	NR	NR	NR
• Statin	607 (67.9)	618 (68.4)	735 (67.5)	491 (67.2)	NR	NR	NR	NR
• Warfarin	310 (34.7)	298 (33.0)	NR	NR	NR	NR	NR	NR
• Other antiarrhythmic	12 (1.3)	8 (0.9)	12 (1.1)	3 (0.4)	NR	NR	30 (35.3)	33 (32.7)

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotension II receptor blocker; CABG, coronary artery bypass graft; CRT-D, cardiac resynchronisation therapy; NYHA, New York Heart Association; NA, not applicable; NR, not reported; SD, standard deviation

Source: Tang et al (2010)[77]; Moss et al (2009)[58]; Linde et al (2008a)[48]; Linde et al (2008b)[50]; Abraham et al (2004)[1]

a Includes patients with an atrial pacemaker.

Table B-9 Baseline characteristics of participants in the European and non-European cohorts of the REVERSE trial

Characteristic	ITT population (N = 610)	European cohort (N = 262)	Non-European cohort (N=348)	P-value[a]
Age, years – mean (SD)	62.5 (11.0)	61.3 (10.4)	63.4 (11.3)	0.02
Male sex – n (%)	479 (78.5)	212 (80.9)	264 (75.9)	0.16
Underlying heart disease – n (%)				
• Ischaemic	333 (54.6)	115 (43.8)	219 (62.9)	<0.0001
• History of myocardial infarction	281 (46.1)	89 (34.0)	191 (54.9)	<0.0001
NYHA class II – n (%)	502 (82.3)	217 (82.8)	285 (81.9)	0.75
LVEF – mean (SD)	26.7 (7.0)	28.0 (6.8)	26.2 (6.4)	0.001
Intrinsic QRS duration – mean (SD)	153.3 (22.0)	156 (23)	151 (21)	0.008
Cardiac risk factors – n (%)				
• Diabetes	137 (22.5)	39 (14.9)	97 (27.9)	<0.0001
• Hypertension	313 (51.3)	89 (34.0)	230 (66.1)	<0.0001
• Peripheral vascular disease	49 (8.0)	13 (5.0)	38 (10.9)	0.02
Medication use – n (%)				
• ACE inhibitor	481 (78.9)	260 (99.2)	254 (73.0)	<0.0001
• ACE inhibitor or ARB	487 (79.8)	225 (85.9)	331 (95.1)	0.0003
• Beta blocker	580 (95.1)	246 (93.8)	334 (96.0)	0.13
• Diuretic	487 (79.8)	223 (85.1)	264 (75.9)	0.006
CRT-D implanted	508 (83.2)	178 (67.9)	331 (95.1)	<0.0001

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotension II receptor blocker; CABG, coronary artery bypass graft; CRT-D, cardiac resynchronisation therapy; NYHA, New York Heart Association; NA, not applicable; NR, not reported; SD, standard deviation
Source: Linde et al (2008b)[50]; Daubert et al (2009)[27]
a European versus non-European comparison

B.4.3 Intervention details and duration of follow-up

Table B-10 compares the specific interventions compared in each of the pivotal and supportive studies. It also presents the mean duration of follow-up within each trial, at the time that the primary endpoint was assessed.

As discussed in **Section B.2**, the pivotal trials, RAFT and MADIT-CRT, directly compared the safety and efficacy of CRT-D implantation (the proposed medical service) to ICD implantation (the main comparator). The supportive trials, REVERSE and MIRACLE ICD II, compared the safety and efficacy of activating or deactivating biventricular pacing in patients who had successfully received a CRT-D (or in some cases CRT-P) implant (i.e. CRT-ON versus CRT-OFF).

In all trials, participants were maintained on optimised medical therapy, which may have included ACE inhibitors, beta-blockers, angiotensin II receptor antagonists and other medications. Specific details of the devices and programming methods used in each trial are provided in footnotes below.

Table B-10 Interventions compared in the direct comparative randomised trials

Study ID	Intervention	Comparator	Duration of follow-up
Pivotal trials			
RAFT	CRT-D implant[a] CRT function activated Optimised medical therapy	ICD implant[a] No CRT function Optimised medical therapy	40 ± 20 months
MADIT-CRT	CRT-D implant[b] CRT function activated Optimised medical therapy	ICD implant[b] No CRT function Optimised medical therapy	34.3 ± 12.2 months
Supportive trials			
REVERSE	CRT-D or CRT-P implant[c] CRT function activated (CRT-ON)[d] Optimised medical therapy	CRT-D or CRT-P implant[c] CRT function deactivated (CRT-OFF)[e] Optimised medical therapy	12 or 24 months
MIRACLE ICD II	CRT-D implant[f] CRT function activated (CRT-ON)[g] Optimised medical therapy	CRT-D implant[f] CRT function deactivated (CRT-OFF)[h] Optimised medical therapy	6 months

Abbreviations: CRT, cardiac resynchornisation therapy; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator

Source: Tang et al (2010)[77]; Moss et al (2009)[58]; Moss et al (2005)[57]; Linde et al (2006)[49]; Linde et al (2008a)[48]; Abraham et al (2004)[1]

a The RAFT trial used commercially available devices and leads (Medtronic) and implantation was performed using standard techniques. During CRT-D implantation, the left ventricular lead was placed within lateral or posterolateral wall of the left ventricle whenever possible. Device programming was standardised to minimise ventricular pacing in the ICD group, maximize ventricular pacing in the CRT-D group, and provide uniform arrhythmia detection and therapy. Details regarding programming measures for the devices are available online at: http://www.nejm.org/doi/suppl/10.1056/NEJMoa1009540/suppl_file/nejmoa1009540_appendix.pdf

b The MADIT-CRT trial used commercially available transvenous leads and devices (Boston Scientific) and implantation was performed using standard techniques. In the CRT–D group, the programmed mode was DDD with a lower rate of 40 bpm and hysteresis off. In the ICD group, the programmed pacing mode was VVI for single-chamber units and DDI for dual-chamber units, with lower rates of 40 bpm and hysteresis off in both single- and dual-chamber units. Further details are available in the trial protocol (Moss et al 2005[57]).

c To receive a CRT-D implant in the REVERSE trial, participants were required to have an indication for an ICD according to US, Canadian or European clinical practice guidelines. The trial used commercially available transvenous leads and devices (Medtronic) and implantation was performed using standard techniques. It was recommended that the left ventricular lead be positioned in the lateral or posterolateral left ventricular wall, midway between the base and apex. If the left ventricular lead implantation was unsuccessful, the trial protocol recommended seeking the assistance of an experienced colleague to increase the potential for a successful reimplant. Epicardial left ventricular lead placements were dis allowed. In total, 83.3% of participants received a CRT-D and 16.7% received an ICD.

d Device programmed to a mode that paced both ventricles and inhibited atrial pacing unless the intrinsic rate was ≤ 35 bpm.

e Device programmed to inhibit atrial or ventricular pacing unless the intrinsic rate was ≤ 35 bpm. Further details are available in the trial protocol (Linde et al 2006[49]).

f Participants in both arms of the MIRACLE ICD II trial were implanted with CRT-D devices (model 7272 InSync ICD, Medtronic).

g Device programmed to a mode that paced both ventricles simultaneously after atrial sensed events at rates of ≤ 130 bpm. Atrial pacing occurred only for sinus rates of ≤ 35 bpm.

h Device programmed to inhibit atrial or ventricular pacing unless the intrinsic rate was < 35 bpm.

B.5 OUTCOME MEASURES AND ANALYSES

B.5.1 Primary outcomes and analyses

Table B-11 defines the primary outcome for each of the identified trials, together with the method of primary statistical analysis.

In the RAFT, MADIT-CRT and REVERSE trials, the primary outcome was defined as a composite of all-cause mortality and/or heart failure events (including hospitalisation for heart failure). Composite end points are often used in cardiology trials to provide an overall estimate of the effect of an intervention. Such outcomes are appropriate under circumstances when multiple end points are considered to be clinically important and/or clinically related. The use of such outcomes can also increase statistical power, decreasing the sample size required (Lim et al 2008[47]).

The MIRACLE ICD II trial was specifically designed to examine whether the addition of CRT to ICD limits disease progression and improves exercise performance in patients with NYHA class II heart failure, compared to ICD alone. The primary outcome was defined as the change in peak oxygen consumption (VO_2) from baseline to six months after randomisation. This is measured in units of $mL \cdot kg^{-1} \cdot min^{-1}$. Peak VO_2 was established to be the oxygen consumption at peak exercise when the respiratory gas exchange ratio (VCO_2/VO_2) was greater than 1.0. In patients with chronic heart failure, this outcome has a strong correlation with both cardiac output and blood flow (Reddy et al 1988[69]).

Table B-11 Primary outcomes and statistical analyses of pivotal and supplementary trials

Trial ID	Definition of primary outcome	Method of primary statistical analysis
Pivotal trials		
RAFT	**Death from any cause or hospitalisation for heart failure** Death from any cause included any death that occurred during the study. Hospitalisation for heart failure was defined as admission to a health care facility lasting more than 24 hours with symptoms of congestive heart failure and subsequent treatment for heart failure.	SAS Software (V 9.2) was used to conduct all statistical analyses. The time in study for each subject started on the day of randomisation and continued until study exit or study completion. All randomised subjects were included in the analysis of the primary objective, regardless of exit status (ITT). Survival data was analysed using Kaplan-Meier product limit estimates, and the nonparametric log-rank test procedure was used for comparing survival curves. The Cox proportional hazards model was used to estimate hazard ratios. The MCID was defined as relative risk reduction of 25%. Pre-specified subgroup analyses included atrial fibrillation versus no atrial fibrillation and NYHA class II versus NYHA class III.
MADIT-CRT	**Death from any cause or non-fatal heart failure event** Heart failure events were defined by symptoms and/or signs consistent with congestive heart failure and: • Required intravenous decongestive therapy > 2 hours (IV diuretics, IV neseritide, IV inotropes), that does not involve formal inpatient hospital admission, regardless of the setting (i.e. in an emergency room setting, in the physician's office, etc); OR • Required an augmented heart failure regimen with oral or intravenous medications during an	ITT analysis using a Wang–Tsiatis (Δ = 0.1 category) group-sequential design with a power of 95% to detect a hazard ratio of 0.75 at a two-sided significance level of 0.05. The trial involved pre-specified event monitoring by an independent data and safety monitoring board at up to 20 successive multiples of approximately 35 adjudicated events (defined in terms of variance of the log-rank statistic), with stopping boundaries specified for termination of the trial in favour of CRT-D, ICD, or for no significant difference. The primary outcome was analysed based on the statistical log-rank test stratified according to

Trial ID	Definition of primary outcome	Method of primary statistical analysis
	in-hospital stay (formal hospital admission is defined as admission to hospital that includes a calendar date change).	study centre and ischemia status. A similarly stratified Cox proportional hazards regression model was used to estimate hazard ratios. Both of these analyses were adjusted for the group-sequential stopping rule and incorporated late reported events that occurred before trial termination. Additional primary analyses included Cox proportional hazards regression for heart failure alone; for death at any time; for evaluation of 10 pre-specified categorical subgroups; and for testing the homogeneity of treatment effect according to time period.
Supportive trials		
REVERSE	**Heart failure clinical composite response (defined by Packer et al 2001[65])** Participants were categorised as "worsened", "unchanged" or "improved" as follows: • Worsened—patient dies; is hospitalised overnight due to or associated with worsening heart failure; permanently discontinues double blind treatment due to or associated with worsening heart failure, treatment failure, or lack of/insufficient therapeutic response; permanently discontinues double blind treatment due to withdrawal of consent or other administrative reason and has worsening HF at the time of study discontinuation; or demonstrates worsening in NYHA class at last observation carried forward or moderate-marked worsening of PGA score at last observation carried forward. • Unchanged—patient is neither improved nor worsened. • Improved—patient has not worsened and demonstrates improvement in NYHA class at last observation carried forward and/or moderate-marked improvement in PGA score at last observation carried forward.	ITT analysis using the chi-square test to compare the per cent of patients worsened in each treatment group. Results were expressed as odds ratios with 95% Wald confidence limits. All P- values were nominal, and all statistical tests were 2-sided. Pre-specified subgroup analyses included a comparison of ischaemic versus non-ischaemic cardiomyopathy. Analyses were conducted with SAS software.
MIRACLE ICD II	**Change in peak VO_2 from baseline to six months** Peak VO_2 was defined as the oxygen consumption at peak exercise when the respiratory gas exchange ratio (VCO_2/VO_2) was < 1.0. VO_2 and VCO_2 were measured during metabolic exercise testing with a breath-by-breath respiratory gas analyser. Cardiopulmonary gas exchange analysis was performed at a core laboratory with personnel blinded to treatment assignment.	ITT analysis with differences between treatment groups compared through the use of the Wilcoxon rank-sum test. A P-value of < 0.05 was considered statistically significant. All probability values were calculated from 2-sided tests. In an analysis that was not pre-specified, potential clinically relevant covariates were analysed by ANOVA with random assignment as independent variables. Investigators had full access to all data and performed analyses without restrictions or limitations from the sponsor.

Abbreviations: ANOVA, analysis of variance; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; ITT, intention-to-treat; IV, intravenous; MCID, minimal clinically important difference; NYHA, New York Heart Association; PGA, Patient's Global Assessment
Source: Tang et al (2009)[76]; Moss et al (2005)[57]; Moss et al (2009)[58]; Linde et al (2006)[49]; Linde et al (2008a)[48]; Abraham et al (2004)[1]

B.5.2 Secondary outcomes and analyses

Table B-12 summarises the secondary outcomes and analyses reported for each of the included studies. Key patient-relevant outcomes are described in further detail below.

Table B-12 Secondary outcomes and statistical analyses of the direct randomised trials

Trial ID	Secondary outcomes	Method of statistical analysis
Pivotal trials		
RAFT	Secondary outcomes: • Death from any cause • Death from a cardiovascular cause • Hospitalisation for any cause • Hospitalisation for a cardiovascular cause • Hospitalisation for heart failure • Device-related hospitalisation • Heart transplantation • AEs occurring within 30 days of implant	SAS Software (V 9.2) was used to conduct statistical analyses. All survival data was analysed using Kaplan-Meier product limit estimates, and the nonparametric log-rank test procedure was used for comparing survival curves. The Cox proportional hazards model was used to estimate hazard ratios. The time in study for each subject started on the day of randomisation and continued until study exit or study completion. All randomised subjects were included in the analysis of the primary objective, regardless of exit status. Safety analyses were performed using the as-treated population. This population included all patients who received CRT-D or CRT therapy, regardless of treatment group assignment.
MADIT-CRT	Secondary outcomes: • Death from any cause • Heart failure events • LV volumes and LVEF • HRQoL (EQ-5D and KCCQ) • AEs within 30 days of implant • AEs during long-term follow-up	ITT analysis using paired-sample t-tests to evaluate the absolute change in LV volumes and LVEF between baseline and 1-year follow-up in patients from each study group who had paired baseline and 12-month recordings. The KCCQ analysis was conducted as a tertiary analysis using feasible generalised least squares methods.
Supportive trials		
REVERSE	Secondary efficacy outcomes: • Death from any cause • Hospitalisation for heart failure • LVESV index (LVESV/body surface area cm/m^2) • Change in NYHA class • 6-minute walk test • HRQoL (MLWHFQ and KCCQ) • Incidence of ventricular arrhythmia recorded by device memory interrogation in the ICD group only • Complications (defined as an AE that resulted in invasive intervention or the termination of significant device function regardless of other treatments)	ITT analysis. All-cause mortality and time to first heart failure hospitalisation analysed using Kaplan-Meier analysis with differences between treatment groups assessed using the log-rank test. Differences in the incidence of ventricular arrhythmias were assessed with the Comparison of Incidence Rates (Large Sample Test). Other secondary end points were compared with the 2-sample t-test. All p values reported were nominal, and all statistical tests were 2-sided. Analyses were conducted with SAS software.

Trial ID	Secondary outcomes	Method of statistical analysis
MIRACLE ICD II	Secondary efficacy outcomes: • Death from any cause • Composite clinical response that assigned all randomised patients to one of three response groups: worsened, improved, or unchanged (Packer et al 1987) • Change in NYHA class • 6-minute walk distance • LV volumes and LVEF • VE/VCO_2 • Complications (defined as a sign, symptom, illness, or other medical event that was resolved invasively or that resulted in the death of or serious injury to a patient. Termination of a significant device function was also considered a complication).	ITT analysis. For continuous outcomes, differences between treatment groups compared through the use of the Wilcoxon rank-sum test. For categorical outcomes, differences in the distribution of responses to treatment at 6 months compared by Fisher's exact test, except for inappropriately detected ventricular tachycardia/ventricular fibrillation episodes for which generalised estimating equation methods were used. A P-value < 0.05 was considered statistically significant. All probability values were calculated from 2-sided tests.

Abbreviations: AE, adverse event; ANOVA, analysis of variance; CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; EQ-5D, Euroqol 5-dimension; HRQoL, health-related quality of life; ICD, implantable cardioverter-defibrillator; ITT, intention-to-treat; KCCQ, Kansas City Cardiomyopathy Questionnaire; LV, veft ventricular; LVEF, left ventricular ejection fraction; MLWHF, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association;
Source: Tang et al (2009)[76]; Tang et al (2010)[77]; Moss et al (2005)[57]; Moss et al (2009)[58]; Veazie at al (2012)[80]; Linde et al (2006)[49]; Linde et al (2008a)[48]; Abraham et al (2004)[1]

All-cause mortality

All-cause mortality is one of the most important outcomes assessed in clinical trials comparing the efficacy and safety of interventions for chronic heart failure. It has the advantage of being a 'hard' endpoint that is easy to measure, not readily subject to observer bias (Zanolla and Zardini et al 2003[84]).

Cardiovascular mortality and sudden cardiac death

Sudden cardiac death is defined as death from cardiac causes occurring unexpectedly within one hour of the onset of symptoms (NICE 2007[60]). None of the identified trials specifically included this as an sudden cardiac death as an endpoint, however the pivotal RAFT and MADIT-CRT trials each reported the number of deaths attributed to a cardiovascular or cardiac cause. Such deaths could include sudden cardiac death, deaths due to pump failure or deaths due to other causes (e.g. myocardial infarction). A blinded, central adjudication committee was responsible for classifying the causes of deaths that occurred within each trial (Tang et al 2010[77], Moss et al 2009[58]).

Rates of hospitalisation

Patients with chronic heart failure have increased morbidity and require frequent hospitalisation. Rates of hospitalisation are therefore frequently included as secondary endpoints in heart failure clinical trials. Hospitalisations are generally adjudicated and classified according to whether they are due to cardiac or non-cardiac causes. Cardiac hospitalisations can be further categorised according to whether they are due to worsening heart failure or other events (e.g. myocardial infarction or comorbidities) (Anand and Florea 2010[6]). All of the identified trials reported rates of hospitalisation for heart failure or rates of heart failure events (including hospitalisation for heart failure and acute episodes that required treatment in a hospital emergency room). Rates of device-related hospitalisations were also reported for the RAFT trial (Tang et al 2010[77]).

Quality of life

The EuroQol 5-Dimension (EQ-5D) instrument is a standardised measure of health status developed by the EuroQol group in order to provide a simple, generic measure of health outcomes for clinical and economic appraisal. It comprises five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Patients are able to tick one of three levels within each dimension which corresponds to their perceived level of health. This instrument was used to assess changes in health-related quality of life among participants in the RAFT and MADIT-CRT trials, however quality of life results from the RAFT trial have not yet been reported. The EQ-5D results of the MADIT-CRT trial are shown in **Appendix D**.

The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess changes in quality of life within the MADIT-CRT and REVERSE trials. This is a 23-item, self-administered instrument that quantifies physical function, symptoms (frequency, severity and recent change), social function, self-efficacy and knowledge, and quality of life in patients with chronic heart failure. Each item is scored on a five-, six- or seven-point Likert scale, with higher scores indicating higher levels of functioning. The quality of life sub-scale is based on an assessment of how much heart failure has limited the patient's enjoyment of life, how the patient would feel about spending the rest of his/her life at his/her current status of heart failure, and the extent the patient has felt discouraged because of his/her heart failure. The KCCQ Clinical Summary score incorporates physical functioning, symptom frequency, and symptom burden. The KCCQ Overall Summary score is based on physical and social functioning, including reported frequency and burden of heart failure symptoms like swelling, fatigue, and shortness of breath (Green et al 2000[36]).

The Minnesota Living with Heart Failure Questionnaire (MLWHFQ) was used to assess changes in quality of life within the REVERSE and MIRACLE ICD II trials. This is a 21-item, heart failure-specific questionnaire that assesses the extent to which heart failure prevented respondents from living as they wanted during the past month. Each item is scored using a six-point Likert scale (0–5), with higher scores indicating that heart failure had a greater impact on activities of daily living. It has been suggested that a 5-point improvement in MLWHFQ score represents a minimal clinically significant change (Rector et al 2005[68]).

NYHA classification

Changes in NYHA class are commonly assessed within heart failure clinical trials as they provide an indication of whether the functional impact of heart failure symptoms has improved or deteriorated since the last assessment. These are determined based on a clinician's interpretation of a patient's reported symptoms and medical history. It should be noted that symptoms can fluctuate even in the absence of treatment, and that inter-observer variability is often high (Zanolla and Zardini 2003[84]).

6-minute walk distance

The 6-minute walk test is a simple, objective measure of exercise capacity. This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes. This distance has been found to predict long-term mortality and heart failure hospitalisation rates in patients with LVSD of varying cause and severity (Bittner et al 1993[16]; Cahalin et al 1996[22]). As the test is self-paced and involves an activity familiar to all subjects, it has been suggested that this provides a better reflection of exercise capacity in patients with heart failure than maximal cardiopulmonary exercise testing (Anand and Florea 2010[6]).

B.6 SYSTEMATIC OVERVIEW OF TRIAL RESULTS

B.6.1 Primary efficacy outcomes

B.6.1.1 RAFT

The primary outcome of the RAFT trial was a composite of death from any cause or hospitalisation for heart failure. Death from any cause included any death that occurred during the study. Hospitalisation for heart failure was defined as an admission to a health care facility lasting more than 24 hours with symptoms of congestive heart failure and subsequent treatment for heart failure. This outcome was assessed at the end of the trial, after a mean follow-up duration of 40 (SD, 20) months (Tang et al 2010[77]).

Within the full population included in the RAFT trial, death from any cause or hospitalisation for heart failure occurred in 33.2% of participants in the CRT-D group, compared to 40.3% of participants in the ICD group (relative risk [RR], 0.83; 95% confidence interval [CI], 0.73 to 0.93; P < 0.002). CRT-D was estimated to reduce the risk of death or heart failure for hospitalisation by 25% (hazard ratio [HR], 0.75; 95% CI, 0.64 to 0.87; P<0.001). Kaplan-Meier curves showing the time to death from any cause, or hospitalisation for heart failure, for all subjects are provided in **Figure B-5**. At five years, the observed rate of death from any cause or hospitalisation for heart failure was 42.4% for CRT-D versus 51.3% for ICD (Tang et al 2010[77]; RAFT CSR[55]).

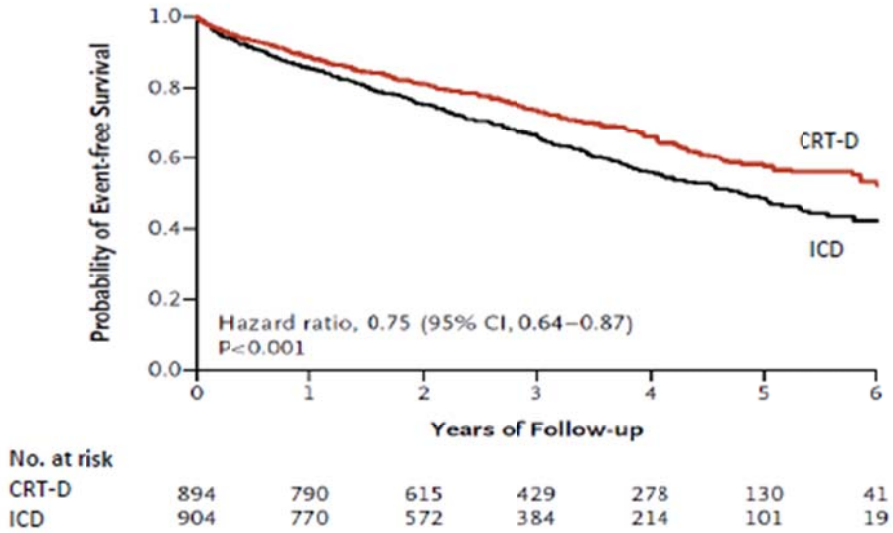
Within the subgroup of patients with NYHA class II heart failure, death from any cause or hospitalisation for heart failure occurred in 27.3% of participants in the CRT-D group, compared to 34.7% of those in the ICD group (RR, 0.71; 95% CI, 0.56 to 0.88; P<0.001). CRT-D was estimated to reduce the risk of death or heart failure for hospitalisation by 27% (HR, 0.73; 95% CI, 0.61 to 0.88); P = 0.001). Kaplan-Meier curves showing the time to death from any cause or hospitalisation for heart failure for the subgroup of patients with NYHA class II heart failure are provided in **Figure B-6**. At five years, the observed rate of death from any cause, or hospitalisation for heart failure, was 40.0% for CRT-D versus 48.1% for ICD (Tang et al 2010[77]; RAFT CSR[55]).

Table B-13 Proportion of patients experiencing death or hospitalisation for heart failure in the RAFT trial (mean follow-up duration of 40 months)

Outcome	CRT-D n/N (%)	ICD n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population (N = 1798)				
Primary outcome:				
• Death from any cause or hospitalisation for heart failure	297/894 (33.2)	364/904 (40.3)	-0.07 (-0.11, -0.03)	0.83 (0.73 to 0.93)
Disaggregated components:				
• All-cause mortality	186/894 (20.8)	236/904 (26.1)	-0.05 (-0.09, -0.01)	0.80 (0.67, 0.94)
• Hospitalisation for heart failure[b]	174/894 (19.5)	236/904 (26.1)	-0.07 (-0.11, -0.03)	0.75 (0.63, 0.89)
NYHA class II subgroup (N = 1438)				
Primary outcome:				
• Death from any cause or hospitalisation for heart failure	193/708 (27.3)	253/730 (34.7)	-0.07 (-0.12, -0.03)	0.71 (0.56, 0.88)
Disaggregated components:				
• All-cause mortality	110/708 (15.5)	154/730 (21.1)	-0.06 (-0.10, -0.02)	0.74 (0.59, 0.92)
• Hospitalisation for heart failure[b]	115/708 (16.2)	159/730 (21.8)	-0.06 (-0.10, -0.01)	0.75 (0.60, 0.93)

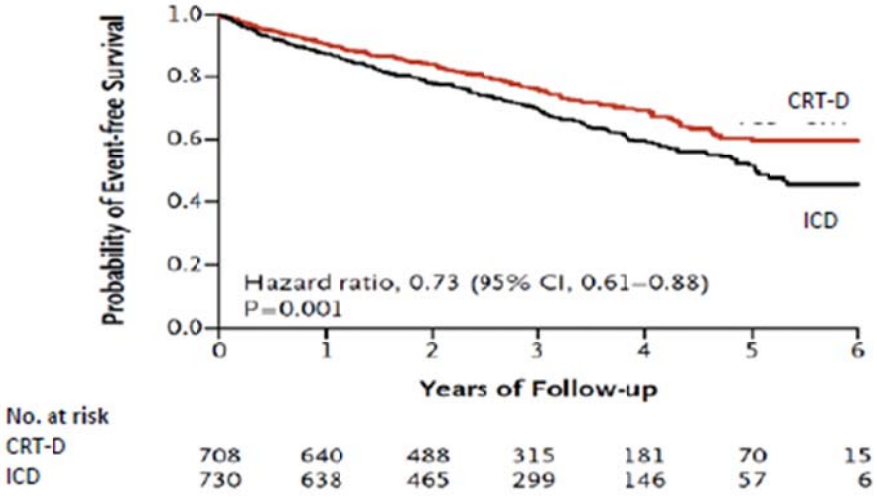
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Table 2
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)
b Defined as an admission to hospital with a diagnosis of worsening heart failure for greater than 24 hours.

Figure B-5 Time to death from any cause or hospitalisation for heart failure in the RAFT trial (ITT population)



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Figure 1A

Figure B-6 Time to death from any cause or hospitalisation for heart failure in the RAFT trial (NYHA class II subgroup)

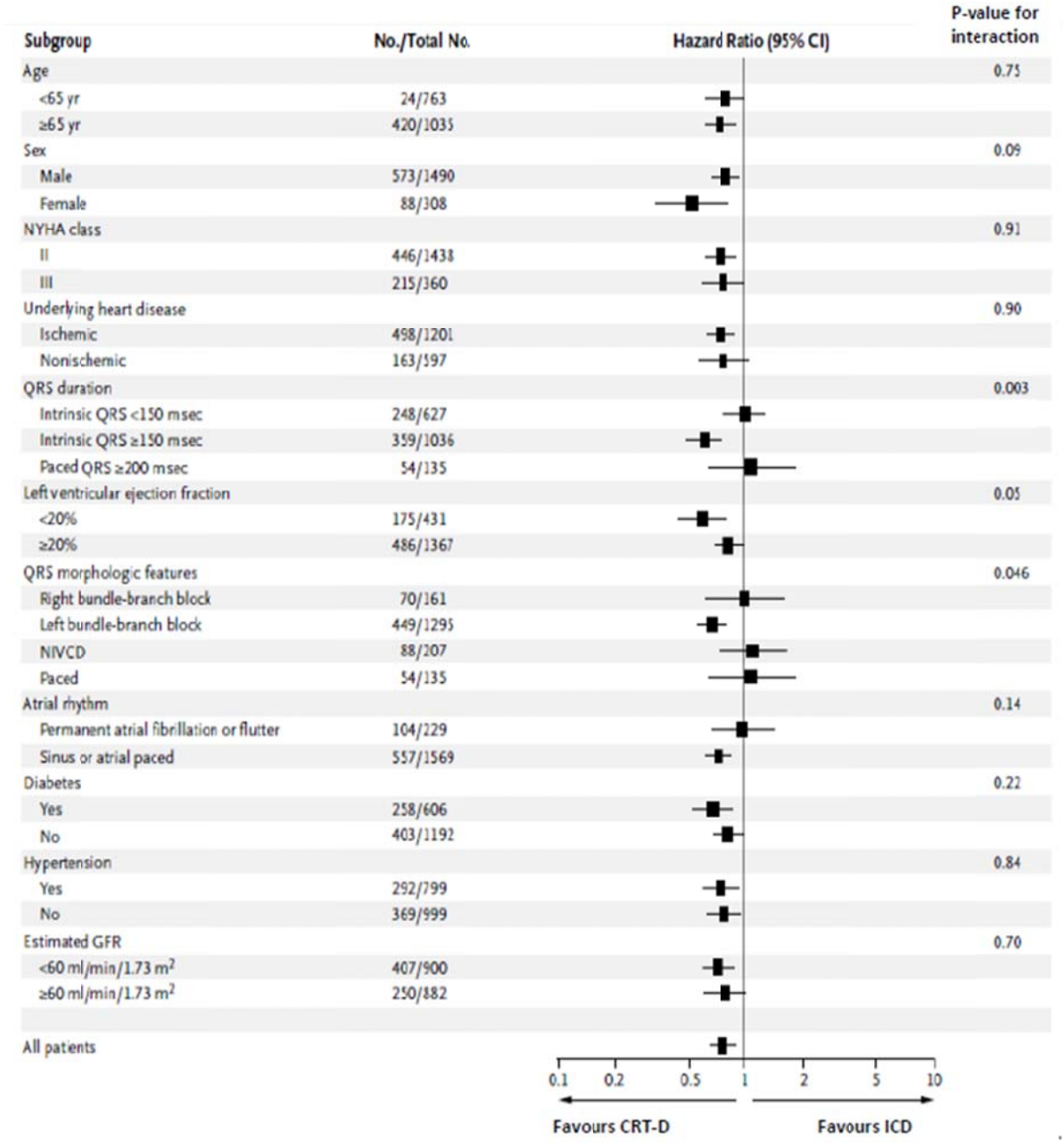


Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Figure 2A

The results of other pre-specified analyses of the primary outcome of the RAFT trial are presented in **Figure B-7**. There was a significant interaction between treatment and QRS duration (P=0.003), with CRT-D being more effective in patients with an intrinsic QRS duration of 150 ms or more (HR, 0.59; 95% CI, 0.48 to 0.73) than in those with an intrinsic QRS duration of less than 150 ms (HR, 0.99; 95% CI, 0.77 to 1.27; P=0.002 for interaction), or patients with a paced QRS duration of 200 ms or more (HR, 1.07; 95% CI, 0.63 to 1.84; P=0.003 for interaction). There was also a weak interaction between treatment efficacy and QRS morphologic type (P = 0.046), with CRT-D being more effective in

patients with left bundle branch block (LBBB) than in those with non-specific intraventricular conduction delay (P = 0.04 for interaction) (Tang et al 2010)[77].

Figure B-7 Proportion of patients experiencing death or hospitalisation for heart failure in the RAFT trial (Subgroup analysis)



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; GFR, glomerular filtration rate; ICD, implantable cardioverter-defibrillator; NIVCD, non-specific intraventricular conduction delay; NYHA, New York Heart Association
Source: Tang et al (2010)[77], Figure 3

B.6.1.2 MADIT-CRT

The primary outcome of MADIT-CRT trial was defined as a composite of death from any cause or a non-fatal heart failure event. Heart failure events were defined by symptoms and/or signs consistent with congestive heart failure and (i) required intravenous decongestive therapy > 2 hours (IV diuretics, IV neseritide, IV inotropes), that does not involve formal inpatient hospital admission, regardless of the setting (i.e. in an emergency room setting, in the physician's office, etc); or (ii) required an augmented heart failure regimen with oral or intravenous medications during an in-hospital stay (Moss et al 2009[58]). This outcome was assessed by an independent data and safety monitoring board at pre-specified intervals. After a mean follow-up duration of 28 months, the MADIT-CRT trial showed that CRT-D significantly reduced the risk of death from any cause or a non-fatal heart failure event in patients with NYHA class I or II heart failure, compared to ICD (Moss et al 2009[58]). Data continued to be collected for six months after this time point, meaning that the total mean duration of follow-up within the MADIT-CRT trial was 34.3 (SD, 12.3) months (MADIT-CRT CSR[17]).

Overall, the primary outcome occurred in 19.1% of participants in the CRT-D group, compared to 28.4% of those in the ICD group (RR, 0.67; 95% CI, 0.57 to 0.79). These results were predominantly driven by a 46% reduction in the risk of heart failure events (HR, 0.54; 95% CI, 0.43 to 0.67; MADIT-CRT CSR[17]). Kaplan-Meier curves showing the time to death from any cause or hospitalisation for heart failure for the ITT population are shown in **Figure B-8**.

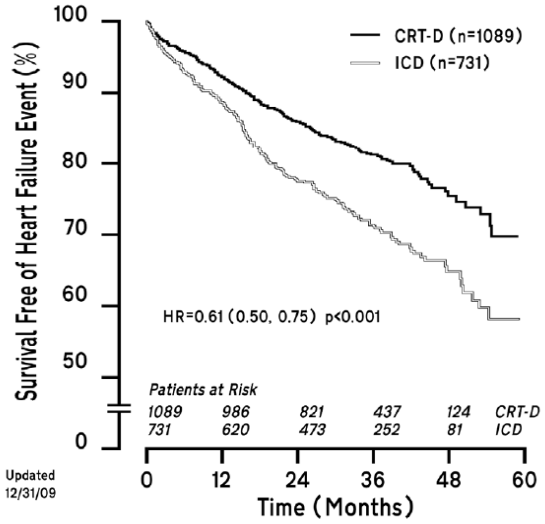
Table B-14 Proportion of patients experiencing death or a non-fatal heart failure event in the MADIT-CRT trial (mean follow-up duration 34 months)

Outcome	CRT-D n/N (%)	ICD n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population (N = 1820)				
Primary outcome:				
• Death from any cause or a non-fatal heart failure event	208/1089 (19.1)	208/731 (28.4)	-0.09 (-0.11, -0.03)	0.67 (0.57, 0.79)
Disaggregated components:				
• Death from any cause[b]	92/1089 (8.4)	68/731 (9.3)	-0.01 (-0.04, 0.02)	0.91 (0.67, 1.22)
• Heart failure event[c]	161/1089 (14.8)	186/731 (25.4)	-0.11 (-0.11, -0.07)	0.58 (0.48, 0.70)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: MADIT-CRT CSR[17], Table 23, page 29

a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects).
b This category includes all deaths, including those that occurred after the first heart failure event.
c Defined by symptoms and/or signs consistent with congestive heart failure that required intravenous decongestive therapy for more than two hours in any setting, or that required an augmented heart failure regimen with oral or intravenous medications during an in-hospital stay.

Figure B-8 Time to death from any cause or non-fatal heart failure event in the MADIT-CRT trial



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: MADIT-CRT CSR[17], Figure 5, page 38

Pre-specified subgroup analyses suggest that CRT-D is associated with a greater benefit in women (HR, 0.37; 95% CI, 0.22 to 0.61) than in men (HR, 0.76; 95% CI, 0.59 to 0.97; P=0.01), and a greater benefit in patients with a QRS duration of 150 ms or more (HR, 0.48; 95% CI, 0.37 to 0.64), compared to those with a QRS duration of less than 150 ms (HR, 1.06; 95% CI, 0.74 to 1.52; P=0.001) (Moss et al 2009[58]). Secondary publications associated with the MADIT-CRT trial have explored differences between these subgroups in further detail (Arshad et al 2011[7]; Barsheshet et al 2011b[14]; Zareba et al 2011[86]). An analysis of the subgroup of participants with NYHA class I or II heart failure and LBBB is included within the clinical study report for the MADIT-CRT trial (**Attachment 2**).

B.6.1.3 REVERSE

The primary outcome of the REVERSE trial was defined as the percentage of participants with worsened clinical composite response at the end of the blinded follow-up period. This was assessed using the composite clinical response system described by Packer et al (2001)[65], which categorises patients as having a 'worsened', 'unchanged' or 'improved' clinical composite response based on an assessment of all-cause mortality, hospitalisation due to or associate with worsening heart failure, crossover due to worsening heart failure, changes in Patient's Global Assessment (PGA) scores, and changes in NYHA class. The primary outcome was assessed 12 months after randomisation for all participants in the REVERSE trial (Linde et al 2008a)[48], and at 24 months after randomisation for participants enrolled within the European cohort (Daubert et al 2009)[27].

Given that the results of the REVERSE trial were not stratified by the type of device initially implanted (CRT-D or CRT-P), it should be noted that the CRT-ON group includes patients receiving the equivalent of CRT-D or CRT-P therapy while the CRT-OFF group includes patients receiving the equivalent of an ICD or no device therapy. The inclusion of patients who received a CRT-P is likely to bias the results of the REVERSE trial against active CRT therapy.

Primary outcome results at 12 months after randomisation (ITT)

Within the ITT population, 83.3% of participants in the REVERSE trial received a CRT-D and 16.7% received a CRT-P. Twelve months after randomisation, 16.0% of participants in the CRT-ON group were classified as having a worsened clinical composite response, compared with 21.5% of participants in the CRT-OFF group (RR, 0.74; 95% CI, 0.53 to 1.06). The disaggregated components of the clinical composite response are shown in **Table B-15.**

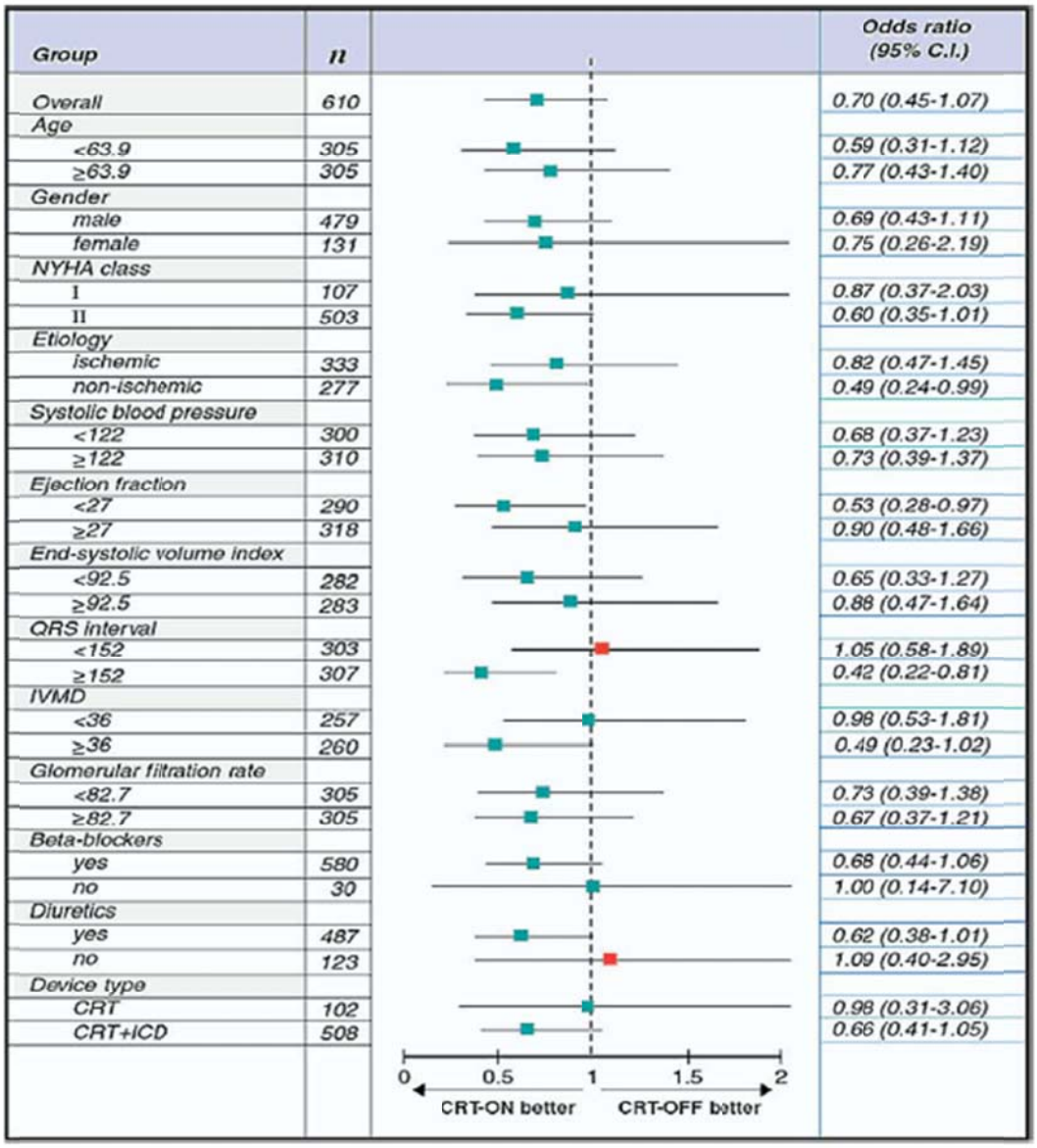
Table B-15 Proportion of patients with worsened clinical composite response in the REVERSE trial (12 month results)

Outcome	CRT-ON n/N (%)	CRT-OFF n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population (N = 610)				
Primary outcome:				
• Worsened clinical composite response[b]	67/419 (16.0)	41/191(21.5)	-0.05 (-0.12, 0.01)	0.74 (0.53, 1.06)
Disaggregated components:				
• Death from any cause	9/419 (2.1)	3/191 (1.6)	0.01 (-0.02, 0.03)	1.37 (0.37, 4.99)
• Hospitalisation due to or associated with worsening heart failure	12/419 (2.9)	14/191 (7.3)	-0.04 (-0.08, -0.00)	0.39 (0.18, 0.83)
• Crossover due to worsening heart failure	1/419 (0.2)	5/191 (2.6)	-0.02 (-0.05, -0.00)	0.09 (0.01, 0.78)
• Worsened NYHA class and PGA	2/419 (0.5)	0/191 (0)	0.00 (-0.01, 0.02)	2.29 (0.11, 47.38)
• Worsened NYHA class only	40/419 (9.5)	18/191 (9.4)	0.00 (-0.05, 0.05)	1.01 (0.60, 1.72)
• Worsened PGA only	3/419 (0.7)	1/191 (0.5)	0.00 (-0.01, 0.01)	1.37 (0.14, 13.06)

Abbreviations: NYHA, New York Heart Association; PGA, Patient's Global Assessment
Source: Linde et al (2008a)[48], Table 2
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)
b Defined by Packer et al (2001)[65]

Although the interactions were not statistically significant, pre-specified subgroup analyses suggested that programming the CRT function to CRT-ON appeared to be associated with a greater benefit among participants who received a CRT-D (OR, 0.66; 95% CI, 0.41 to 1.05), compared to those who received a CRT-P (OR, 0.98; 95% CI, 0.31, 3.06); a greater benefit among participants with NYHA class II heart failure (OR, 0.60; 95% CI, 0.35 to 1.01), compared to those with NYHA class I heart failure (OR 0.87; 95% CI, 0.37 to 2.03); and a greater benefit among participants with QRS duration of 152 ms or more (OR, 0.42; 95% CI 0.22 to 0.81) than in those with a QRS duration of less than 152 ms (OR, 1.05; 95% CI 0.58 to 1.89) (Linde et al 2008a[48]) (**Figure B-9**).

Figure B-9 Proportion of patients with worsened clinical composite response in the REVERSE trial (Subgroup analysis, 12 month results)



Abbreviations: CRT, cardiac resynchronisation therapy device; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; IVMD, intraventricular mechanical delay; NYHA, New York Heart Association
Source: Linde et al (2008a)[48], Figure 4

Primary outcome results at 24 months after randomisation (European cohort)

The European cohort of the REVERSE trial was followed for 24 months before being unblinded. Within this cohort, 68% of participants received a CRT-D and 32% received a CRT-P. Fewer participants in the CRT-ON group were classified as having a worsened clinical response, compared to the CRT-OFF group (RR, 0.55; 95% CI, 0.36 to 0.85). This was attributed to the higher rate of death from any cause or hospitalisation due to or associated with worsening heart failure occurring in the CRT-OFF group. An analysis of the distribution of heart failure clinical composite response levels (i.e. worsened, unchanged, and improved) yielded a P-value of 0.0006 at 24 months in favour of CRT-ON (Daubert et al 2009[27]).

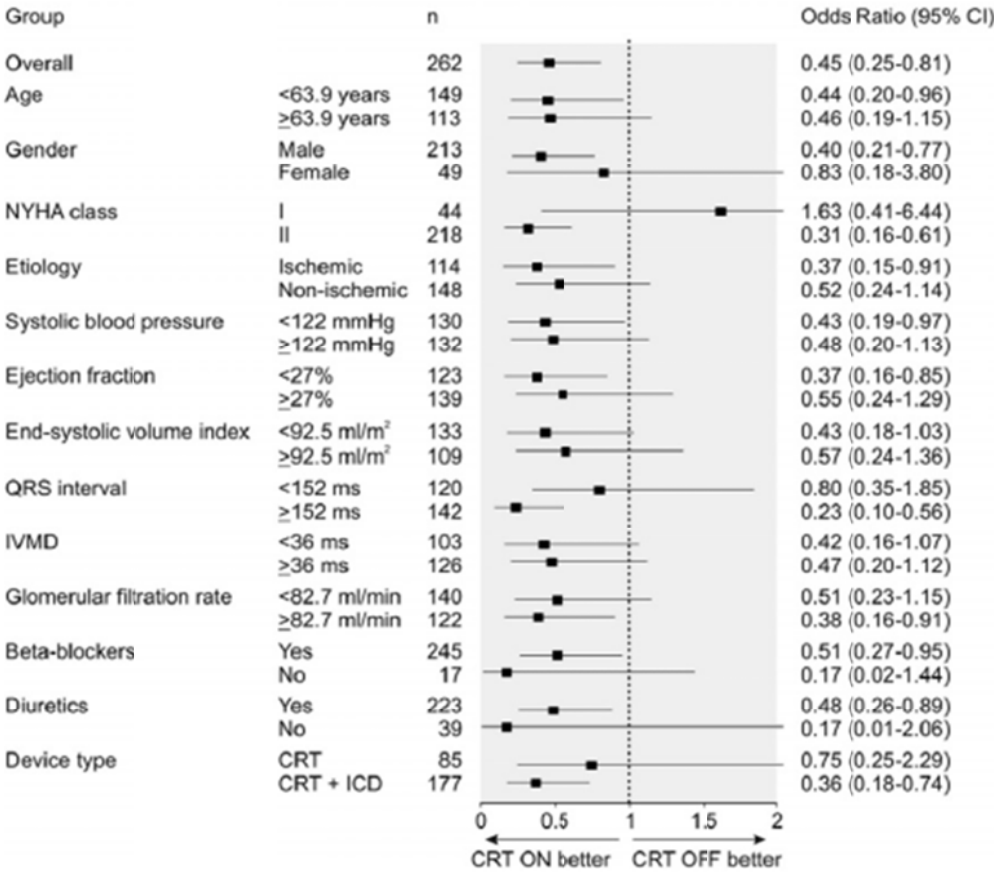
Table B-16 Proportion of patients with worsened clinical composite response in the European cohort of the REVERSE trial (24 month results)

Outcome	CRT-ON n/N (%)	CRT-OFF n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
Primary outcome:				
• Worsened clinical composite response[b]	34/180 (18.9)	28/82 (34.1)	-0.15 (-0.27, -0.04)	0.55 (0.36, 0.85)
Disaggregated components:				
• Death from any cause	4/180 (2.2)	7/82 (8.5)	-0.06 (-0.13, 0.00)	0.26 (0.08, 0.86)
• Hospitalisation due to or associated with worsening heart failure	12/180 (6.7)	12/82 (14.6)	-0.08 (-0.16, 0.01)	0.46 (0.21, 0.97)
• Crossover due to worsening heart failure	0/180 (0)	2/82 (2.4)	-0.02 (-0.06, 0.01)	0.09 (0.00, 1.89)
• Worsened NYHA class and PGA	1/180 (0.6)	1/82 (1.2)	-0.01 (-0.03, 0.02)	0.46 (0.03, 7.19)
• Worsened NYHA class only	15/180 (8.3)	5/82 (6.1)	0.02 (-0.04, 0.09)	1.37 (0.51, 3.63)
• Worsened PGA only	2/180 (1.1)	1/82 (1.2)	-0.00 (-0.03, 0.03)	0.91 (0.08, 9.91)

Abbreviations: NYHA, New York Heart Association; PGA, Patient's Global Assessment
Source: Daubert et al (2009)[27], Figure 2
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)
b Defined by Packer et al (2001)[65]

Subgroup analyses showed that the odds ratio for experiencing a worsened composite clinical response was 0.36 (95% CI, 0.18 to 0.74) for the subgroup of participants who received a CRT-D, versus 0.75 (95% CI, 0.25 to 2.29) for those who received a CRT-P. The level of improvement in clinical status conferred by CRT appears to be greater among patients with NYHA class II heart failure compared to NYHA class I, however this comparison was unreliable because of an insufficient number of observations. Patients with a QRS duration of 152 ms or more derived a greater benefit from CRT than patients with a QRS of less than or equal to 152 ms (**Figure B-10**; Daubert et al 2009[27]).

Figure B-10 Proportion of patients with worsened clinical composite response in the European cohort of the REVERSE trial (Subgroup analysis, 24 month results)



Abbreviations: CRT, cardiac resynchronisation therapy device; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; IVMD, intraventricular mechanical delay; NYHA, New York Heart Association
Source: Daubert et al (2009)[27], Figure 4

B.6.1.4 MIRACLE ICD II

The primary outcome of the MIRACLE ICD II trial was defined as the change in peak oxygen consumption (VO_2) from baseline to six months after randomisation. This outcome is used as an indicator of exercise capacity and the strength of cardiac output, and is measured in units of mL/kg/min. Mean peak VO_2 levels increased by 0.5 mL/kg/min (SD 3.2) for participants in the CRT-ON group, compared with 0.2 mL/kg/min (SD 3.2) for participants in the CRT-OFF group, with no significant difference between treatment arms (P=0.87) (Abraham et al 2004[1]). The study authors note that that this finding is not surprising as participants in the MIRACLE ICD II trial had only mild symptoms of chronic heart failure at baseline. While active CRT did not alter the primary outcome, it did significantly improve echocardiographic outcomes and overall clinical status as discussed in **Section B.6.2.4**.

B.6.2 Secondary efficacy outcomes

B.6.2.1 RAFT

Table B-17 summarises the secondary efficacy results of the RAFT trial. These were assessed after a mean follow-up duration of 40 months. All-cause mortality, cardiovascular mortality and hospitalisation results are discussed in further detail below.

Table B-17 Summary of secondary efficacy results of the RAFT trial

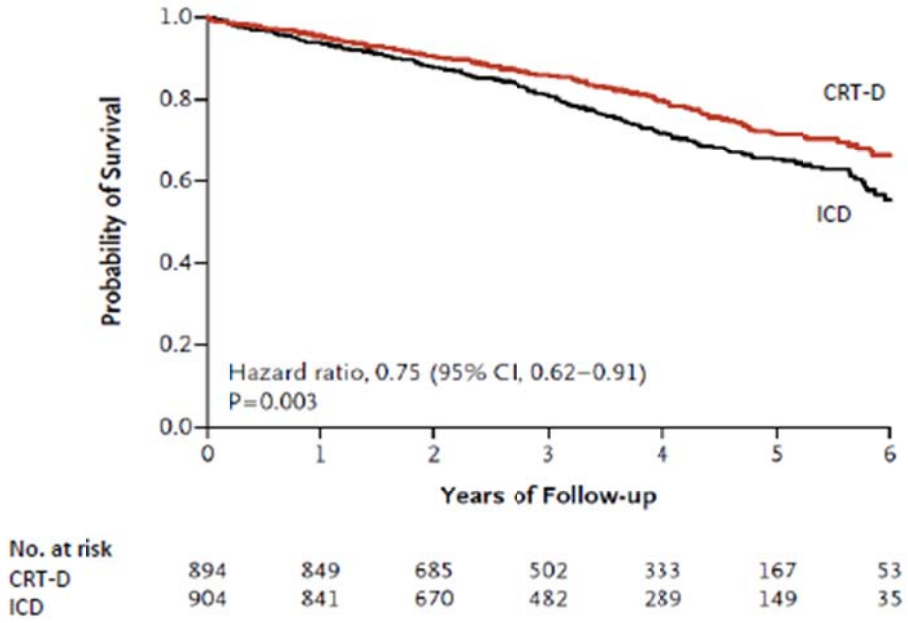
Outcome	CRT-D n/N (%)	ICD n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population (N = 1798)				
Mortality outcomes:				
• Death from any cause	186/894 (20.8)	236/904 (26.1)	-0.05 (-0.09, -0.01)	0.80 (0.67, 0.94)
• Death from a cardiovascular case	130/894 (14.5)	162/904 (17.9)	-0.03 (-0.07, 0.00)	0.81 (0.66, 1.0)
Hospitalisation outcomes:				
• Hospitalisation for any cause	509/894 (56.9)	509/904 (56.0)	0.01 (-0.04, 0.05)	1.01 (0.93, 1.10)
• Hospitalisation for a cardiovascular cause	423/894 (47.3)	404/904 (44.7)	0.03 (-0.02, 0.07)	1.06 (0.96, 1.17)
• Hospitalisation for heart failure	174/894 (19.5)	236/904 (26.1)	-0.07 (-0.11, -0.03)	0.75 (0.63, 0.89)
• Device-related hospitalisation	179/894 (20.0)	110/904 (12.2)	0.08 (0.04, 0.11)	1.65 (1.32, 2.05)
• Heart transplantation	7/894 (0.8)	5/904 (0.6)	0.00 (-0.01, 0.001)	1.42 (0.45, 4.44)
NYHA class II subgroup (N = 1438)				
Number of participants	708/894 (79.2)	730/904 (80.1)	-	-
Death from any cause or hospitalisation for heart failure	193/708 (27.3)	253/730 (34.7)	-0.07 (-0.12, -0.03)	0.79 (0.67, 0.92)
Mortality outcomes:				
• Death from any cause	110/708 (15.5)	154/730 (21.1)	-0.06 (-0.10, -0.02)	0.74 (0.59, 0.92)
• Death from a cardiovascular cause	74/708 (10.5)	100/730 (13.7)	-0.03 (-0.07, 0.00)	0.76 (0.58, 1.01)
Hospitalisation for heart failure	115/708 (16.2)	159/730 (21.8)	-0.06 (-0.10, -0.01)	0.75 (0.60, 0.93)

Abbreviations: CI, confidence interval; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association
Source: Tang et al (2010)[77]
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

All-cause mortality

During a mean follow-up duration of 40 months, 186 of 894 (20.8%) participants in the CRT-D group died, compared with 236 of 904 (26.1%) participants in the ICD group (RR, 0.80; 95% CI, 0.67 to 0.94; P<0.01). The five-year actuarial mortality rate was 28.6% for the CRT-D group versus 34.6% for the ICD group (HR, 0.75; 95% CI, 0.62 to 0.91; P=0.003). It was estimated that 14 patients would need to be treated for five years with a CRT-D in order to prevent one death (Tang et al 2010[77]). Kaplan-Meier estimates of time to death from any cause for the ITT population of the RAFT trial are shown in **Figure B-11**. At five years, the all-cause mortality rate was 28.6% for CRT-D versus 34.6% for ICD (RAFT CSR).

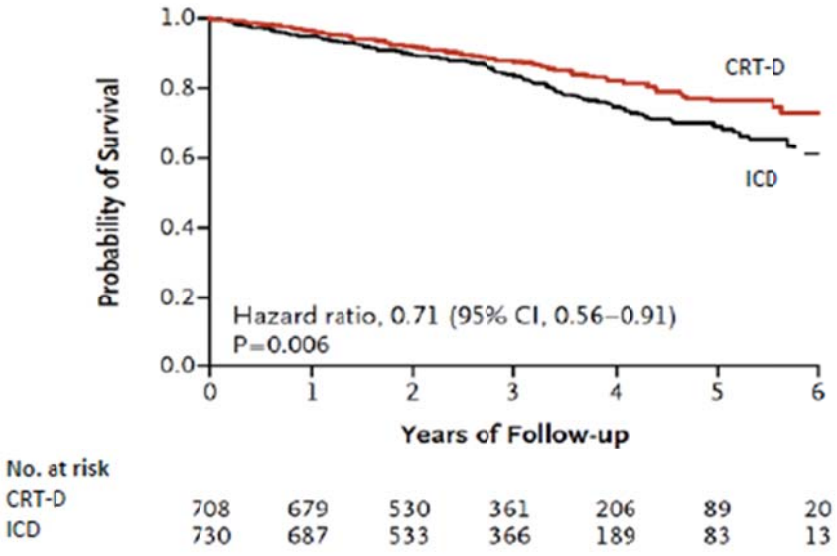
Figure B-11 Time to death from any cause in the RAFT trial (ITT)



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Figure 1B
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

Within the subgroup of patients with NYHA class II heart failure, 110 of 708 (15.5%) participants in the CRT-D group died, compared with 154 of 730 (21.1%) participants in the ICD group (RR, 0.74; 95% CI, 0.59 to 0.92; P=0.007). Kaplan-Meier estimates of time to death from any cause for the subgroup of patients with NYHA class II heart failure are shown in **Figure B-12**. At five years, the all-cause mortality rate was 23.7% for CRT-D versus 31.0% for ICD (HR, 0.71; 95% CI, 0.56 to 0.91; P=0.006).

Figure B-12 Time to death from any cause in the RAFT trial (NYHA class II subgroup)



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77], Figure 1C
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

Cardiovascular mortality

Death from a cardiovascular cause accounted for 69.2% of all deaths that occurred during the RAFT trial. Within the ITT population, 14.5% of participants in the CRT-D group died due to a cardiovascular cause, compared with 17.9% of those in the ICD group (RR, 0.81; 95% CI, 0.66 to 1.0). CRT-D was estimated to reduce the risk of death from a cardiovascular cause by 24% (HR, 0.76; 95% CI, 0.60 to 0.96; P=0.02). The five-year cardiovascular mortality rate was 22.5% for CRT-D versus 25.5% for ICD (RAFT CSR[55]).

Within the subgroup of patients with NYHA class II heart failure, 10.5% of participants in the CRT-D group died due to a cardiovascular cause, compared with 13.7% of those in the ICD group (RR, 0.76; 95% CI, 0.58 to 1.01). CRT-D was estimated to reduce the risk of death from a cardiovascular cause by 27% within this subgroup (HR, 0.73; 95% CI, 0.54 to 0.99). The five-year cardiovascular mortality rate was 17.8% for CRT-D versus 22.2% for ICD (RAFT CSR[55]).

Hospitalisation for heart failure

The RAFT trial defined hospitalisation for heart failure as admission to a health care facility lasting more than 24 hours with symptoms of congestive heart failure and subsequent treatment for heart failure. This outcome occurred in 19.5% of participants within the CRT-D group and 26.1% of participants of participants in the ICD group (RR, 0.75; 95% CI, 0.63 to 0.89). The hazard ratio for hospitalisation for heart failure was 0.68 in favour of CRT-D (95% CI, 0.56 to 0.83; P<0.001) and the five-year rate of hospitalisation for heart failure was 28.6% for CRT-D versus 36.6% for ICD (RAFT CSR[55]).

Within the subgroup of patients with NYHA class II heart failure, hospitalisation for heart failure occurred in 16.2% of participants in the CRT-D group and 21.8% of participants in the ICD group (RR, 0.75; 95% CI, 0.60 to 0.93). The hazard ratio for hospitalisation for heart failure for this subgroup was 0.70 in favour of CRT-D (P=0.003) and the five-year rate of hospitalisation for heart failure was 25.7%% for CRT-D versus 33.3% for ICD (RAFT CSR[55]).

Device-related hospitalisations

Although the RAFT trial did not specifically define 'device-related hospitalisation' as an outcome, the primary publication (Tang et al 2010[77]) notes that participants in the CRT-D group had a higher number of device-related hospitalisations than those in the ICD group (20.0% versus 12.2%; HR, 1.68; 95% CI, 1.32 to 2.13; P<0.001).

B.6.2.2 MADIT-CRT

All-cause and cause-specific mortality

During a mean follow-up duration of 34 months, 8.4% of participants in the CRT-D group of the MADIT-CRT trial died, compared to 9.3% of those in the ICD group (RR, 0.91; 95% CI, 0.67 to 1.22). The causes of deaths occurring in each treatment group are summarised in **Table B-18**. Although sudden cardiac death was not specifically reported as an outcome, death due to a cardiac arrhythmic cause accounted for a smaller proportion of deaths occurring in the CRT-D group (7.6% of all deaths), compared to the ICD group (11.8% of all deaths) (MADIT-CRT CSR[17]).

Table B-18 Summary of mortality results of the MADIT-CRT trial

Outcome	CRT-D n/N (%)	ICD n/N (%)
ITT population (N = 1820)		
Death from a cardiac cause	46/1089 (4.2)	43/731 (5.9)
• Arrhythmic cause	7/1089 (0.6)	8/731 (1.1)
• Ischaemic cause	6/1089 (0.6)	2/731 (0.3)
• Pump failure	32/1089 (2.9)	30/731 (4.1)
• Other cardiac procedure	-	2/731 (0.3)
• Other cardiac cause	1/1089 (0.1)	1/731 (0.1)
Death from a non-cardiac cause	33/1089 (3.0)	16/731 (2.2)
Cause of death not classified	4/1089 (0.4)	2/731 (0.3)
Cause of death unknown	9/1089 (10.3)	7/731 (1.0)
Death from any cause	**92/1089 (8.4)**	**68/731 (9.3)**

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: MADIT-CRT CSR[17], Table 5

Heart failure events

Heart failure events were defined as symptoms and/or signs consistent with congestive heart failure that required intravenous decongestive therapy for more than two hours in any setting, or that required an augmented heart failure regimen with oral or intravenous medications during an in-hospital stay. Such events occurred in 14.8% of participants in the CRT-D group, versus 25.4% of participants in the ICD group (RR, 0.58; 95% CI, 0.48 to 0.70), with the majority of heart failure events occurring in the inpatient setting. CRT-D reduced the risk of experiencing a heart failure event by 46% (HR, 0.54; 95% CI, 0.43. 0.67; P<0.001), and reduced the risk of experiencing recurrent heart failure events by 32% (HR, 0.68; 95% CI 0.54 to 0.85; P<0.001), compared to ICD (MADIT-CRT CSR[17]).

Table B-19 Heart failure event rates observed in the MADIT-CRT trial

Outcome	CRT-D n/N (%)	ICD n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population (N = 1798)				
Heart failure event[b]	161/1089 (14.8)	186/731 (25.4)	-0.11 (-0.11, -0.07)	0.58 (0.48, 0.70)
• Inpatient setting	144/1089 (13.2)	155/731 (21.2)	-0.08 (-0.12, -0.04)	0.62 (0.51, 0.77)
• Outpatient setting	14/1089 (1.3)	31/731 (4.2)	-0.03 (-0.05, -0.01)	0.30 (0.16, 0.57)
Number of heart failure events:				
• 0	928/1089 (85.2)	545/731 (74.6)	0.11 (0.07, 0.14)	1.14 (1.09, 1.20)
• 1	93/1089 (8.5)	107/731 (14.6)	-0.06 (-0.09, -0.03)	0.58 (0.45, 0.76)
• 2+	68/1089 (6.2)	79/731 (10.8)	-0.05 (-0.07, -0.02)	0.58 (0.42, 0.79)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: MADIT-CRT CSR[17], Table 23; MADIT-CRT CSR[17], Table 25
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)
b Defined by symptoms and/or signs consistent with congestive heart failure that required intravenous decongestive therapy for more than two hours in any setting, or that required an augmented heart failure regimen with oral or intravenous medications during an in-hospital stay.

Quality of life

The EQ-5D results of the MADIT-CRT trial were published in a secondary publication that evaluated the cost-effectiveness of CRT-D implantation versus ICD implantation within the context of the trial. These results are shown below in **Table B-21**., and are also discussed in **Section C.4**.

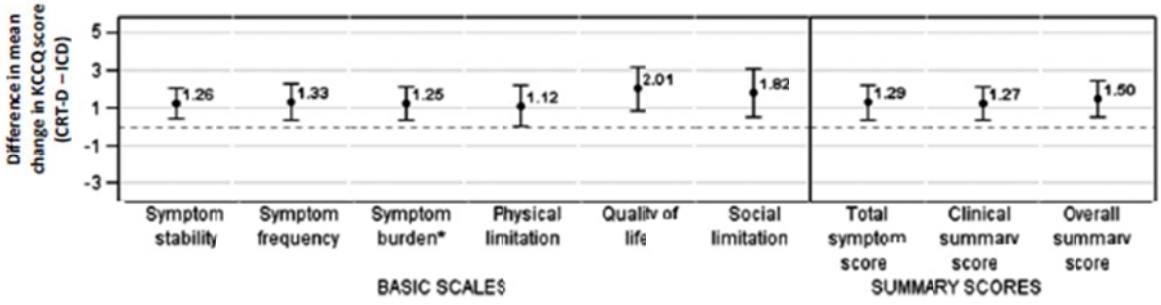
Table B-20 EQ-5D results of the MADIT-CRT trial

Outcome	CRT-D	ICD
Mean EQ-5D index score at baseline	0.848 (SD 0.314)	0.845 (SD 0.134)
Mean EQ-5D index score during follow-up[a]	0.884 (SD 0.145)	0.874 (SD 0.145)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; EQ-5D, EuroQol 5-Dimension; ICD, implantable cardioverter-defibrillator; SD, standard deviation
Source: Noyes et al (2013)[63], Table 2
a Mean of all EQ-5D index scores measured from 6 to 28 months after implantation.

The KCCQ results of the MADIT-CRT trial were published in as part of a separate substudy that used feasible generalised least squares regression was used to test differences between changes in KCCQ scores reported for participants in the CRT-D group compared with the changes in KCCQ scores reported for participants in the ICD group (Veazie et al 2012[80]). These results are shown below in **Figure B-13**. Participants in the CRT-D group had a significantly greater improvement in heart failure specific quality of life than those in the ICD group as assessed on the symptom stability, symptom frequency, symptom burden, physical limitation, quality of life, and social limitation KCCQ basic scales, and as assessed by determination of Total Symptom, Clinical Summary, and Overall Summary scores (P<0.05 on each scale). The results of the KCCQ analysis are consistent with the EQ-5D results reported by Noyes et al (2013)[63], in that patients in the CRT-D group had significantly improved quality of life, compared to those in the ICD group, although the magnitude of change is small.

Figure B-13 Difference in effect of CRT-D versus ICD implantation on mean changes in Kansas Cardiomyopathy Questionnaire scores in the MADIT-CRT trial

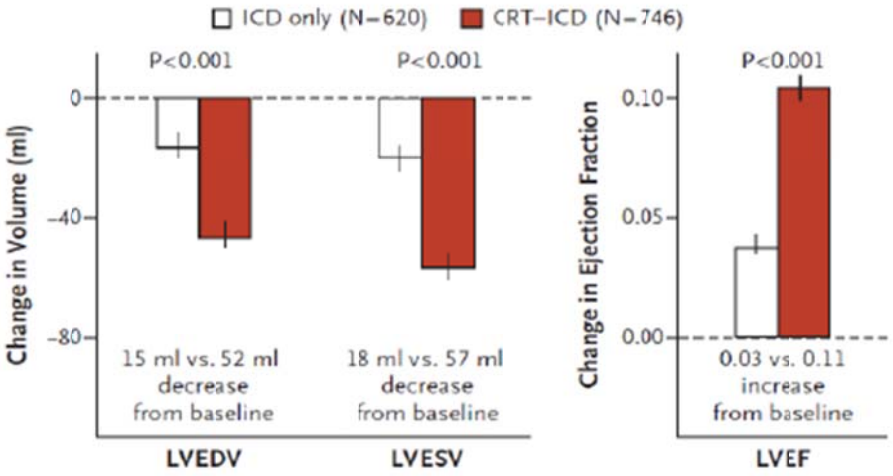


Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Veazie et al (2012)[80], Figure 1
a Differences in effect is defined as the change from baseline for the CRT-D group minus change from baseline for the ICD group. Results have been adjusted for baseline systolic and diastolic blood pressure levels. N = 1699.

Measures of cardiac size and contractile function

Paired-sample analyses of mean changes in echocardiographic left ventricular volumes and LVEF are shown in **Figure B-14**. These analyses included 746 participants in the CRT-D group (68.5%) and 620 participants in the ICD group (84.8%). After a mean follow-up duration of 29 months, mean changes in LVEDV, LVSEV and LVEF from baseline were significantly greater among participants in the CRT-D group than in the ICD group (P<0.001). These measures indicate that participants in the CRT-D group had improved cardiac size and contractile function, compared with those in the ICD group (Moss et al 2009[58]). The contractile function and ventricular remodeling results of the MADIT-CRT trial have been explored in detail by Solomon et al (2010)[75], Knappe et al (2011)[43] and Kutiyifa et al (2013)[45].

Figure B-14 Changes in left ventricular volumes and left ventricular ejection fraction observed in the MADIT-CRT trial



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Moss et al (2009)[58], Figure 4

B.6.2.3 REVERSE

Table B-21 summarises the mortality, hospitalisation and clinical composite results of the REVERSE trial as reported for the ITT population at 12 months after randomisation (Linde et al 2008a[48]), and for the European cohort at 24 months after randomisation (Daubert et al 2009[27]). These results were not stratified by the type of device initially implanted. The CRT-ON group includes patients receiving the equivalent of CRT-D or CRT-P therapy while the CRT-OFF group includes patients receiving the equivalent of an ICD or no device therapy. The results of the REVERSE trial are therefore biased in favour of the CRT-OFF group.

Table B-21 Summary of mortality, hospitalisation and clinical composite results of the REVERSE trial

Outcome	CRT-ON n/N (%)	CRT-OFF n/N (%)	Risk difference (95% CI)[a]	Relative risk (95% CI)[a]
ITT population, 12 month results (N = 1820)				
Death from any cause	9/419 (2.1)	3/191 (1.6)	0.01 (-0.02, 0.03)	1.37 (0.37, 4.99)
Hospitalisation due to or associated with worsening heart failure	12/419 (2.9)	14/191 (7.3)	-0.04 (-0.08, -0.00)	0.39 (0.18, 0.83)
Improved clinical composite response	228/419 (54.4)	76/191 (39.8)	0.15 (0.06, 0.23)	1.37 (1.13, 1.66)
• Improved NYHA class and PGA	69/419 (16.5)	11/191 (5.8)	0.11 (0.06, 0.16)	2.86 (1.55, 5.28)
• Improved NYHA class only	59/419 (14.1)	28/191 (14.7)	-0.01 (-0.07, 0.05)	0.96 (0.63, 1.46)
• Improved PGA only	100/419 (23.9)	37/191 (19.4)	0.04 (-0.02, 0.11)	1.23 (0.88, 1.72)
Unchanged clinical composite response	124/419 (29.6)	74/191 (38.7)	-0.09 (-0.17, -0.01)	1.23 (0.88, 1.72)
European cohort, 24 month results (N = 262)				
Death from any cause	4/180 (2.2)	7/82 (8.5)	-0.06 (-0.13, 0.00)	0.26 (0.08, 0.86)
Hospitalisation due to or associated with worsening heart failure	12/180 (6.7)	12/82 (14.6)	-0.08 (-0.16, 0.01)	0.46 (0.21, 0.97)
Improved clinical composite response	97/180(53.9)	24/82 (29.3)	0.25 (0.12, 0.37)	1.84 (1.28, 2.65)
• Improved NYHA class and PGA	37/180 (20.6)	8/82 (9.8)	0.11 (0.02, 0.20)	2.11 (1.03, 4.32)
• Improved NYHA class only	18/180 (10.0)	8/82 (9.8)	0.00 (-0.08, 0.08)	1.02 (0.46, 2.26)
• Improved PGA only	42/180 (23.3)	8/82 (9.8)	0.14 (0.05, 0.22)	2.39 (1.18, 4.86)
Unchanged clinical composite response	49/180 (27.2)	30/82 (36.6)	-0.09 (-0.22, 0.03)	0.74 (0.51, 1.08)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association

Source: Linde et al (2008a)[48], Table 2; Daubert et al (2009)[27], Figure 4

a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

All-cause mortality

Within the ITT population, 2.1% of participants in the CRT-ON arm of the REVERSE trial died during the first 12 months after randomisation, compared with 1.6% of those in the CRT-OFF arm. The relative risk of death from any cause was not statistically significant (RR, 1.37; 95% CI 0.37, 4.99) (Linde et al 2008a[48]).

During 24 months of follow-up, however, 2.2% of participants in the CRT-ON arm of the European cohort of the REVERSE trial died, compared with 8.5% of those in the CRT-OFF arm. Participants in the CRT-ON group had a significantly lower risk of death from any cause than those in the CRT-OFF group (RR, 0.26; 95% CI 0.08, 0.86) (Daubert et al 2009[27])

Hospitalisation for worsening heart failure

At 12 months after randomisation, 2.9% of participants in the CRT-ON group of the REVERSE trial had been hospitalised due to worsening heart failure, compared to 7.3% of those in the CRT-OFF group (RR, 0.39 95% CI, 0.18 to 0.83). The time to first hospitalisation for heart failure was significantly prolonged in favour of CRT-ON (HR, 0.47; P=0.03).

At 24 months after randomisation, 6.7% of participants in the CRT-ON group of the European cohort of the REVERSE trial had been hospitalised due to worsening heart failure, compared to 14.6% of those in the CRT-OFF group (RR, 0.46; 95% CI 0.21 to 0.97). The CRT-ON group had a significantly prolonged time to first hospitalisation for heart failure (HR, 0.39; P<0.01).

Other secondary outcomes

Table B-22 and **Figure B-15** summarises other key secondary efficacy results of the REVERSE trial. These suggest that participants in the CRT-ON group experienced less adverse ventricular remodeling than those in the CRT-OFF group, and that active CRT did not have a significant effect on 6-minute walk distance or quality of life measured using the MLWHFQ or KCCQ (Linde et al 2008a[48]; Daubert et al 2009[27]). Episodes of ventricular tachycardia or ventricular fibrillation occurred at a rate of 0.57 per year in the CRT-D group (196 episodes in 54 of 345 participants), versus 0.70 per year in the ICD group (114 episodes in 163 participants; P= 0.09) (Linde et al 2008a[48]).

Table B-22 Summary of other secondary efficacy results of the REVERSE trial (12 and 24 month results)

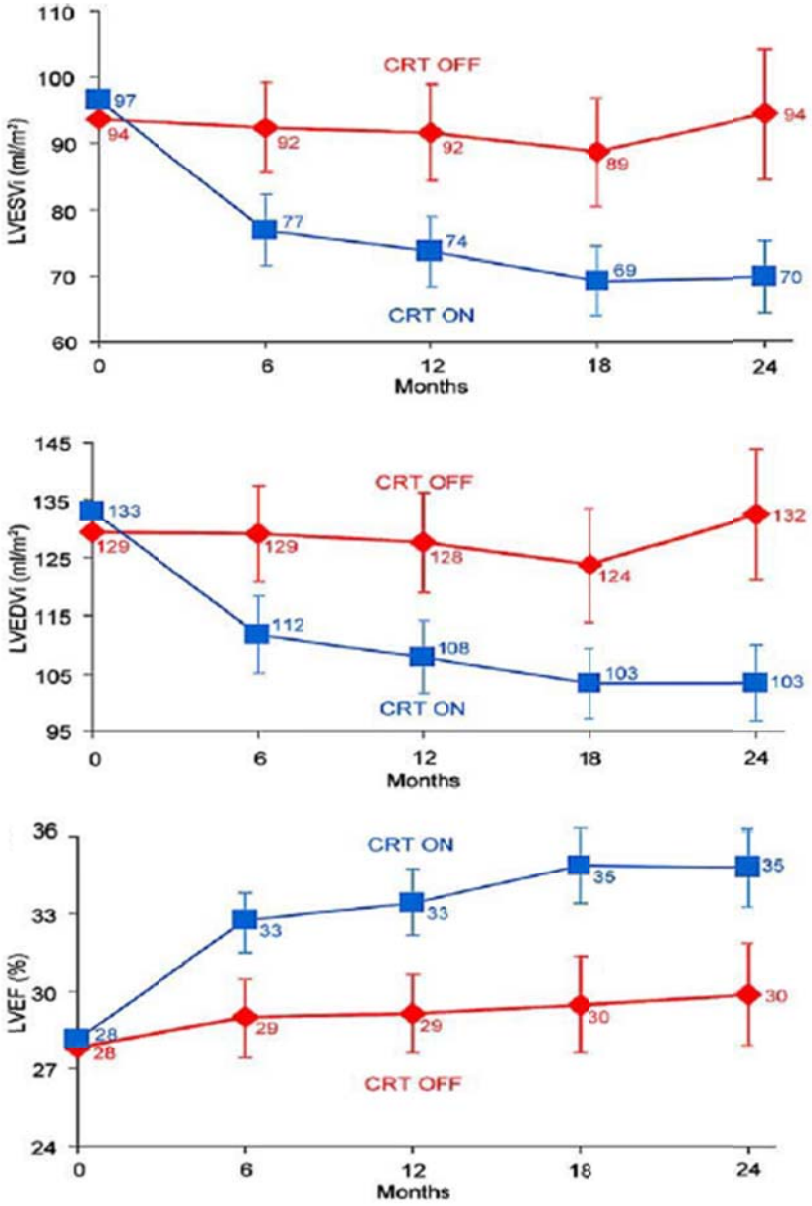
Outcome	CRT-ON		CRT-OFF		P-value
	n/N (%)	Mean (SD)	n/N (%)	Mean (SD)	
ITT population, 12 month results (N = 1820)					
Change in LVESVI, mL/m^2	324/419 (77.3)	-18.4 (29.5)	163/191 (85.3)	-1.3 (23.4)	0.0001
Change in intraventricular mechanical delay, ms	276/419 (65.9)	-13.0 (43.2)	140/191 (73.3)	0.2 (34.0)	0.0007
Change in 6-minute walk distance, m	NR	12.7 (102.4)	NR	18.7 (105.2)	0.52
Change in MLWHF score	NR	-8.4 (17.1)	NR	-6.7 (15.9)	0.26
Change in KCCQ score	NR	8.7 (17.8)	NR	8.5 (16.1)	0.91
European cohort, 24 month results (N = 262)					
Change in LVESVI, mL/m^2	136/180 (71.3)	-27.5 (31.8)	51/82 (62.2)	-2.7 (25.8)	0.0001
Change in 6-minute walk distance, m	NR	29.2 (87.3)	NR	21.9 (90.7)	0.57
Change in MLWHF score	NR	-8.2 (15.5)	NR	-7.0 (14.6)	0.62

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVESVI, left ventricular end systolic volume-index; MLWHF, Minnesota Living with Heart Failure Questionnaire

Source: Linde et al (2008a)[48], Table 2; Daubert et al (2009)[27]

a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

Figure B-15 Changes in mean LVESVI, LVEDVI and LVEF observed in the European cohort of the REVERSE trial (24 month results)



Abbreviations: LVEDVI, left ventricular end diastolic volume-index; LVEF, left ventricular ejection fraction; LVESVI, left ventricular end systolic volume-index
Source: Daubert et al (2009)[27], Figure 3

B.6.2.4 MIRACLE ICD II

The composite clinical response system described by Packer et al (2001)[65] was used to assign participants to one of three clinical response categories: improved, worsened or unchanged. **Table B-23** summarises the relative proportions of participants with in each response category at six months after randomisation. Overall, 20.0% of participants in the CRT-D group were classified as having a worsened overall clinical status, compared with 30.7% of those in the ICD group.

Table B-23 Relative proportion of patients with an improved, unchanged or worsened clinical status in the MIRACLE ICD II trial

Outcome	CRT-ON n/N (%)	CRT-OFF n/N (%)
All-cause mortality	2/85 (2.4)	2/101 (2.0)
Change in overall clinical status		
• Improved	49/85 (57.6)	36/101 (35.6)
• Unchanged	19/85 (22.4)	34/101 (33.7)
• Worsened	17/85 (20.0)	31/101 (30.7)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Abraham et al (2004)[1], Table 2

Other secondary efficacy results of the MIRACLE ICD II trial are summarised in **Table B-24**. At six months after randomisation, participants in the CRT-ON group had improved exercise time and 6-minute walk distance, but these results were not statistically different from the CRT-OFF group. Echocardiographic assessments showed that participants in the CRT-ON group had significantly reduced left ventricular end diastolic and end systolic volumes and a significantly improved LVEF.

Table B-24 Summary of other secondary efficacy results of the MIRACLE ICD II trial

Outcome	CRT-ON		CRT-OFF		P-value
	n/N (%)	Mean (SD)	n/N (%)	Mean (SD)	
Change in exercise duration, s	66/85 (77.6)	0.5 (3.2)	79/110 (71.8)	37 (186)	0.56
Change in VE/VCO^2, mL/min	66/85 (77.6)	42 (167)	78/110 (70.9)	0.5 (5.2)	0.01
Change in NYHA class	82/85 (96.5)	-0.18 (0.61)	98/110 (89.1)	0.01 (0.63)	0.05
Change in MLWHF score	81/85 (95.3)	-13.3 (25.1)	96/110 (87.2)	-10.7 (21.7)	0.49
Change in 6-min walk distance, m	78/85 (91.8)	38 (109)	93/110 (84.5)	33 (98)	0.59
Echocardiographic outcomes:					
• Change in LVEDV, mL	69/85 (81.2)	-41 (76)	85/110 (77.3)	-16 (62)	0.04
• Change in LVESV, mL	68/85 (80.0)	-42 (77)	85/110 (77.3)	-14 (57)	0.01
• Change in LVEF, absolute %	68/85 (80.0)	3.8 (8.0)	85/110 (77.3)	0.8 (6.2)	0.02
• Change in mitral regurgitation	62/85 (72.9)	-1.7 (4.7)	84/110 (76.4)	-1.0 (3.7)	0.25
Change in QRS duration, ms	78/85 (91.8)	-9 (24)	95/110 (86.4)		0.97
Changes in plasma neurohormones, pg/mL					
• BNP	64/85 (75.3)	-195.2 (831.6)	71/110 (64.5)	-96.3 (581.6)	0.81
• Dopamine	60/85 (70.6)	-10.3 (59.7)	71/110 (64.5)	5.5 (18.2)	0.26
• Norepinephrine	60/85 (70.6)	10.1 (396.0)	71/110 (64.5)	63.3 (248.3)	0.86
• Epinephrine	60/85 (70.6)	-6.5 (34.2)	71/110 (64.5)	-4.7 (25.8)	0.67
• Big endothelin	61/85 (71.8)	-2.3 (15.6)	70/110 (63.6)	-4.3 (17.8)	0.69

Abbreviations: BNP, brain natriuretic peptide; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LVEDV, LVEF, left ventricular ejection fraction; left ventricular end diastolic volume; LVESV, left ventricular end systolic function; MLWHF, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association
Source: Abraham et al (2004)[1], Table 2
a Calculated post-hoc using Review Manager v5.1 (Mantel-Haenszel method, assuming random effects)

B.6.3 Safety outcomes

B.6.3.1 RAFT

One participant in the ICD arm of the RAFT trial died from worsening heart failure within 24 hours of device implantation. During the first 30 days after device implantation, there were 118 device- or implantation-related complications among the 888 participants who received a CRT-D implant, versus 61 among 899 participants in the ICD group (**Table B-25**). These complications included haemothorax or pneumothorax, device-pocket haematoma requiring intervention, device-pocket infection requiring intervention, lead dislodgement requiring intervention, device-pocket problems requiring revision, and coronary sinus dissection, all of which occurred more frequently in the CRT-D group (Tang et al 2010[77]). At the time of preparing this application, long-term safety data had not been reported for this trial.

Table B-25 System-related complications occurring within 30 days of implantation in the RAFT trial

Outcome	CRT-D n/N (%)	ICD n/N (%)
Any AE during first 30 days after implant	118/888 (13.3)	61/899 (6.8)
• Coronary sinus dissection	11/888 (1.2)	0/898 (0)
• Device-pocket haematoma requiring intervention	14/888 (1.6)	11/899 (1.2)
• Device-pocket infection requiring intervention	21/888 (2.4)	16/899 (1.8)
• Device-pocket problems requiring revision	4/888 (0.5)	1/898 (0.1)
• Haemothorax or pneumothorax	11/888 (1.2)	8/899 (0.9)
• Heart failure exacerbation requiring IV medication and prolonged hospitalisation	5/888 (0.6)	3/899 (0.3)
• Lead dislodgement requiring intervention	61/888 (6.9)	20/899 (2.2)
• Other AE requiring prolonged hospitalisation	1/888 (0.1)	0/899 (0)
• Tamponade	1/888 (0.1)	2/899 (0.2)

Abbreviations: AE, adverse event; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77]

B.6.3.2 MADIT-CRT

In total, 1079 of the 1820 participants enrolled in the MADIT-CRT trial underwent a CRT-D or ICD implant procedure. Of these, 144 participants experienced system-related complications (SRCs) within the first 30 days post-implant; 14 participants experienced SRCs between 31 and 60 days, and six participants experienced SRCs between 61 and 91 days. The system-related complication-free rate for participants in the CRT-D group was 84.8% with a lower one-sided 95% confidence bound of 82.9%. This was statistically significantly greater the pre-specified safety boundary of 70%, therefore it was concluded that CRT-D systems are safe in patients with NYHA class I or II heart failure, a LVEF of less than 30%, and QRS duration of 130 ms or more (MADIT-CRT CSR[17]).

Serious adverse events occurring in the first 30 days post-implant are summarised in **Table B-26**. These included pneumothorax, infection, device-pocket haematoma requiring evacuation and coronary venous dissection with pericardial effusion. During long-term follow-up after the first 30 days, serious device-related adverse events occurred with a frequency of 4.5 per 100 device-months in the CRT-D group versus 5.2 per 100 device-months in the ICD group (Moss et al 2009[58]).

Table B-26 Serious adverse events occurring within 30 days of implantation in the MADIT-CRT trial

Outcome	CRT-D[a]	ICD[a]
SAE during first 30 days after implant		
• Pneumothorax	1.7%	0.8%
• Infection	1.1%	0.7%
• Device-pocket haematoma requiring evacuation	3.3%	2.5%
• Coronary venous dissection with pericardial effusion	0.5%[b]	NA
• Complication requiring repositioning of left ventricular lead	4.0%[c]	NA

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; NA, not applicable; SAE, serious adverse event
Source: Moss et al (2009)[58]
a n/N not reported
b n = 5
c n = 44

B.6.3.3 REVERSE

The REVERSE trial defined a complication as an adverse event that resulted in invasive intervention or the termination of significant device function regardless of other treatments was classified as a complication. **Table B-27** summarises the frequency of procedure or system-related complications occurring during the first 12 months after implantation. Complication rates did not differ between treatment groups (P=0.64) and were reported for the trial population as a whole.

During or just before implantation, a total of 26 procedure or system-related complications occurred among the 642 participants who underwent a CRT-D (83.3%) or CRT-P (16.7%) implant attempt. Twenty-five of these complications were resolved within 28 days of onset. The most common peri-operative complications were adverse drug reactions, pneumothorax and atrial fibrillation or flutter (4 cases each).

After implantation and during the 12-month follow-up period, 101 of the 621 successfully implanted patients experienced a total of 138 procedure or system-related complications. The most common post-implant complications were lead dislodgements (66 cases) and inappropriate device irritation of tissue (e.g. diaphragmatic nerve stimulation, 14 cases). At the time of database closure for the primary analysis, 128 (93%) of post-implant complications were resolved (66% within three weeks of onset), seven were ongoing, two were unresolved with no further actions expected, and one resulted in death.

A total of 66 left ventricular lead-related complications occurred among 59 patients. In 48 cases these required reoperation (8% of successfully implanted patients). The most common types of left ventricular lead-related complications were left ventricular lead dislodgements (41 cases), diaphragmatic stimulation (14 cases), and subclavian vein thrombosis (3 cases). In 86% of cases, these complications were resolved without untoward clinical effects (Linde et al 2008a[48]).

Table B-27 Procedure or system-related complications occurring within 12 months after CRT-D implantation in the REVERSE trial

Outcome	n/N (%)[a]
Procedure or system-related complications during or just before implant	26/642 (4.0)
• Adverse drug reaction	4/642 (0.6)
• Pneumothorax	4/642 (0.6)
• Atrial fibrillation or flutter	4/642 (0.6)
• Pulmonary oedema	2/642 (0.3)
• Ventricular fibrillation	2/642 (0.3)
• Complete heart block	2/642 (0.3)
• Cardiac tamponade	1/642 (0.2)
• Pericardial effusion	1/642 (0.2)
• Hypotension	1/642 (0.2)
• Increased defibrillation threshold	1/642 (0.2)
Procedure or system-related complications during the first 12 months after implant[b]	101/621 (16.3)
• Left ventricular lead dislodgement	41/621 (6.6)
• Right ventricular lead dislodgement	15/621 (2.4)
• Right atrial lead dislodgement	10/621 (1.6)
• Inappropriate device irritation of tissue	14/621 (2.3)
• Atrial fibrillation or flutter	8/621 (1.3)
• Implant site haematoma	5/621 (0.8)
• Hypotension	4/621 (0.6)
• Pericardial effusion	4/621(0.6)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; SAE, serious adverse event

Source: Moss et al (2009)[58]

a Of the 684 participants enrolled in the REVERSE trial, 642 underwent an implant attempt and 621 were successfully implanted with a CRT or CRT-D device. Only those with a successful implant were included in the randomised phase of the study.

b After implantation and during the 12-month follow-up, 101 of the 621 successfully implanted patients experienced a total of 138 procedure or system-related complications. At the time of database closure, 128 (93%) of the 138 complications were resolved, 7 were ongoing, 2 were unresolved and one resulted in death.

Within the European cohort of the REVERSE trial, device-related serious adverse events occurred among 9.2% of participants during the 24-month blinded follow-up period. The percentage of patients with serious adverse events in the CRT-ON versus CRT-OFF study groups was similar (P=0.66). Between 1 and 12 months after implantation serious adverse event rate was 6%, with the most common adverse event being lead dislodgement. The rate of serious adverse events between 12 and 24 months after implantation was 3%, consisting mainly of right ventricular lead dysfunction (Daubert et al 2009[27]).

B.6.3.4 MIRACLE ICD II

The MIRACLE ICD II trial collected data on the frequency of complications, defined as a sign, symptom, illness, or other medical event that was resolved invasively or that resulted in the death of or serious injury to a patient, including termination of a significant device function. Of the 210 participants who underwent CRT-D implantation in the MIRACLE ICD II trial, 46 participants (22%) experienced 56 complications from the time of implant to discharge. Nineteen complications were related to placement of the left ventricular lead, including three coronary sinus dissections, three cardiac perforations, and five lead dislodgements. From hospital discharge to the end of the six month randomisation period, 109 complications occurred in 66 of 191 participants (35%) with a successful implant, of which 19 related to the left ventricular lead (Abraham et al 2004[1]).

B.7 EXTENDED ASSESSMENT OF COMPARATIVE HARMS

The primary analysis of safety outcomes associated with medical services performed for CRT-D and ICD implantation comes from the analysis of system-related complications and serious adverse events observed within 30 days of implantation in the pivotal RAFT and MADI-CRT trials (**Section B.6.3.1** and **Section B.6.3.2**). Data to support the long-term safety of CRT-D implantation comes from the REVERSE trial (**Section B.6.3.3**).

A focused literature search was conducted to support the extended assessment of comparative harms associated with CRT-D versus ICD implantation. This search specifically sought to identify evidence from systematic reviews and post-marketing surveillance studies regarding the risk of rare or delayed adverse events. Five systematic reviews were identified that included pooled analyses of safety data from comparative trials of CRT-D, CRT-P or ICD implantation across all NYHA classes (Al-Majed et al 2011[3]; Bertoldi et al 2011[15]; Van Rees et al 2011[79]). The characteristics and results of these studies are summarised in **Table B-28**.

Table B-28 Summary of studies included in the extended assessment of comparative harms

Study ID	Summary of study characteristics	Summary of safety results
Pooled analyses of adverse events associated with CRT-D, CRT-P or ICD implantation across all NYHA classes		
Adabag 2011[2]	Systematic review and meta-analysis of 8 trials that compared CRT-D versus ICD in patients with NYHA class I or II heart failure.Includes pooled analysis of the rate of AEs occurring within 30 days of implant in RAFT and MADIT-CRT.	*Pooled analysis of AEs occurring within 30 days of implant in the RAFT and MADIT-CRT trials* Peri-operative mortality: 0.05% for CRT-D vs. 0.06% for ICD Pneumothorax: 1.5% for CRT-D vs. 0.8% for ICD Pocket haematoma: 2.5% for CRT-D vs. 1.8% for ICD Pocket infection: 1.7% for CRT-D vs. 1.3% for ICD LV lead dislodgement: 5.1% for CRT-D Coronary sinus dissection: 0.8% for CRT-D Any AE within 30 days: 18.2% for CRT-D vs. 4.0% for ICD
Al-Majed 2011[3]	Systematic review and meta-analysis of 25 trials that compared CRT-D or CRT-P versus ICD or OMT in patients with heart failure (includes RAFT and MADIT-CRT). Includes pooled analysis of complication rates associated with CRT-D or CRT-P implantation.	*Pooled analysis of complication rates associated with CRT-D or CRT-P implantation across all NYHA classes* Implant success rate: 94.4% (95% CI, 93.8-94.8%) Peri-operative mortality: 0.3% (95% CI, 0.2-0.5%) Mechanical complications: 3.2% (95% CI, 2.8-3.6%)[a] Device malfunction: 1.9% (95% CI, 1.5-2.4%)[b] Lead problems: 6.2% (95% CI, 5.6-6.8%)[c] Infection: 1.4% (95% CI, 1.1-1.7%)
Bertoldi 2011[15]	Systematic review and meta-analysis of 11 trials that compared CRT-D or CRT-P versus ICD or OMT in patients with heart failure (includes RAFT and MADIT-CRT). Includes pooled analysis of complication rates associated with CRT-D or CRT-P implantation.	*Pooled analysis of complication rates associated with CRT-D or CRT-P implantation across all NYHA classes* Implant failure rate: 8% (95% CI, 6-11%) Any major peri-implant complication: 13.2% (95% CI, 7.3-23.9%) Implant-related mortality: 0.6% (95% CI, 0.2-2.2%) Rate of peri-implant complications related to the left ventricular lead: 3% (95% CI, 1-8.7%) The rate of all types of implant-related complication showed a progressive decline from earlier to more recent studies. Restricting analysis to trials published after 2004 reduced the pooled risks of implant failure to 6.3% (95% CI, 4.3-9.2%), any peri-implant complication to 9.8% (95% CI, 6.3-15.4%), complications related to left ventricular lead to 1.8% (95% CI, 0.7-4.5%), and implant-related mortality to 0.2% (95% CI, 0.1-0.9%).

Study ID	Summary of study characteristics	Summary of safety results
Tu 2011[78]	Systematic review and meta-analysis of 8 trials that compared CRT-D or CRT-P versus ICD or OMT in patients with heart failure (all NYHA classes). Includes pooled analysis of complication rates associated with CRT-D or CRT-P implantation versus ICD implantation in RAFT, MADIT-CRT and the European cohort of the REVERSE trial.	Overall RR for complications associated with CRT-D or CRT-P implantation versus ICD implantation: 1.74 (95% CI, 1.44, 2.11) RR for complications occurring within 30 days of implant in RAFT and MADIT-CRT, for CRT-D implantation versus ICD implantation: 1.79 (95% CI, 1.47, 2.18)
Van Rees 2011[79]	Systematic review and meta-analysis of implantation-related complication rates reported in 18 CRT-D, CRT-P or ICD implantation studies. Published one month before RAFT.	*Pooled analysis of in-hospital mortality* Thoracotomy and nonthoracotomy ICD systems: 2.7% Nonthracotomy ICD systems: 0.2% Nonthoracotomy CRT-D or CRT-P systems: 0.3% *Pooled analysis of death within 30 days of implant* Thoracotomy and nonthoracotomy ICD systems: 3.1% Nonthracotomy ICD systems: 0.6% Nonthoracotomy CRT-D or CRT-P systems: 0.7% *Pooled analysis of pneumothorax* Nonthracotomy ICD systems: 0.9% Nonthoracotomy CRT-D systems: 0.9% *Pooled analysis of coronary vein dissection, perforation or tamponade associated with CRT-D or CRT-P implant* *Perforation or Tamponade* *2.0%* *Pooled analysis of implant site haematoma or bleeding* Thoracotomy and nonthoracotomy ICD systems: 4.7% Nonthracotomy ICD systems: 2.2% Nonthoracotomy CRT-D systems: 2.4% *Lead dislodgement* Nonthracotomy ICD systems: 1.8 Nonthoracotomy CRT-D systems: 5.7

Abbreviations: AEs, adverse events; CI, confidence interval; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; CRT-P, cardiac resynchronisation therapy device; ICD, implantable cardioverter-defibrillator; LV, left ventricular; NYHA, New York Heart Association; OMT, optimised medical therapy; RR, relative risk

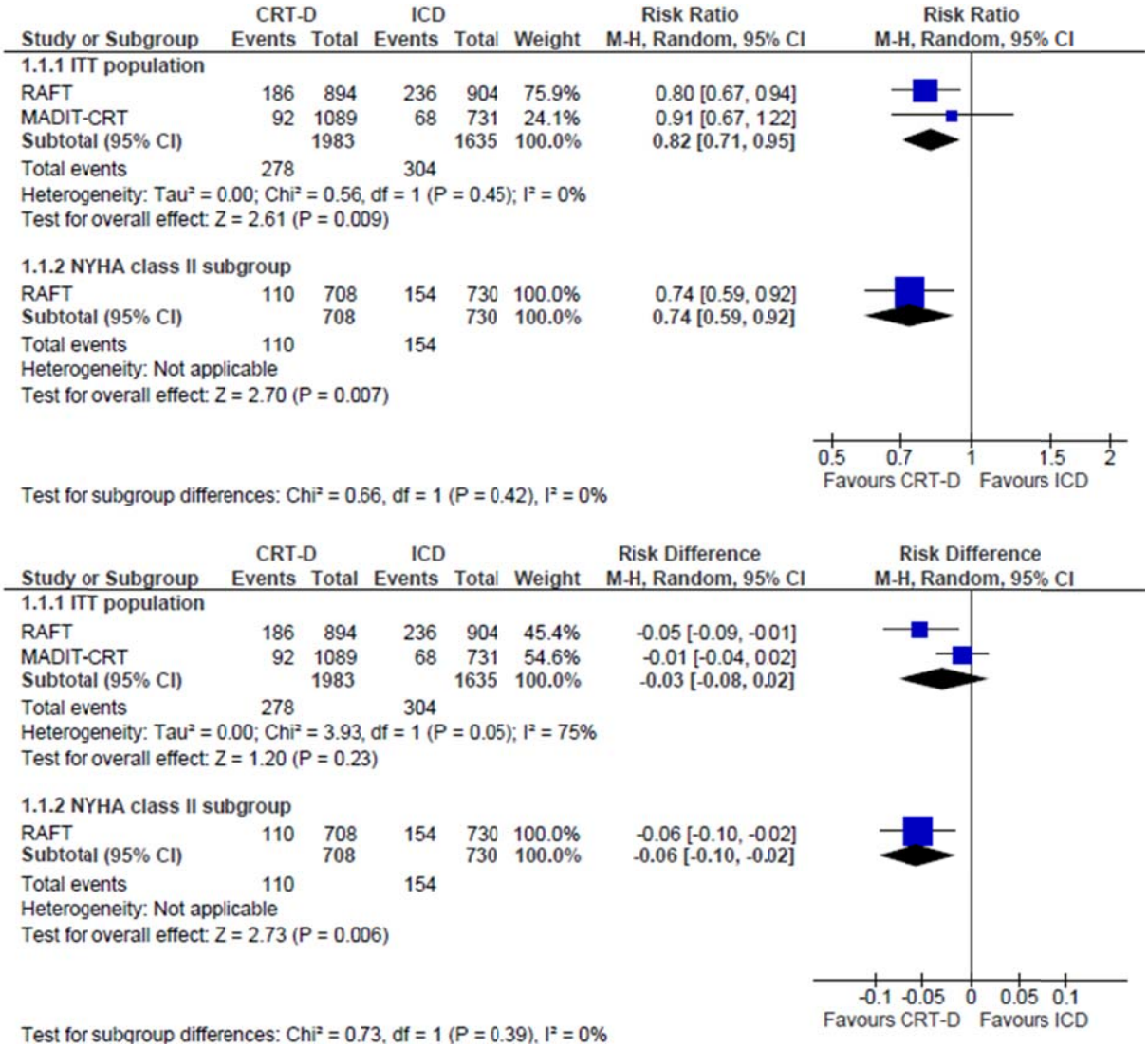
No post-marketing studies were identified that specifically assessed the long-term safety of CRT-D or ICD implantation in patients with NYHA class II heart failure. It is noted that potential adverse events may include rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, lead or accessory breakage, and inappropriate shock (**Section A.6**).

B.8 SUMMARY OF CLINICAL EVIDENCE

This submission requests an MBS listing for the medical services relating to the insertion, removal or replacement of a CRT-D for patients with NYHA class II heart failure, a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more, despite optimised medical therapy.

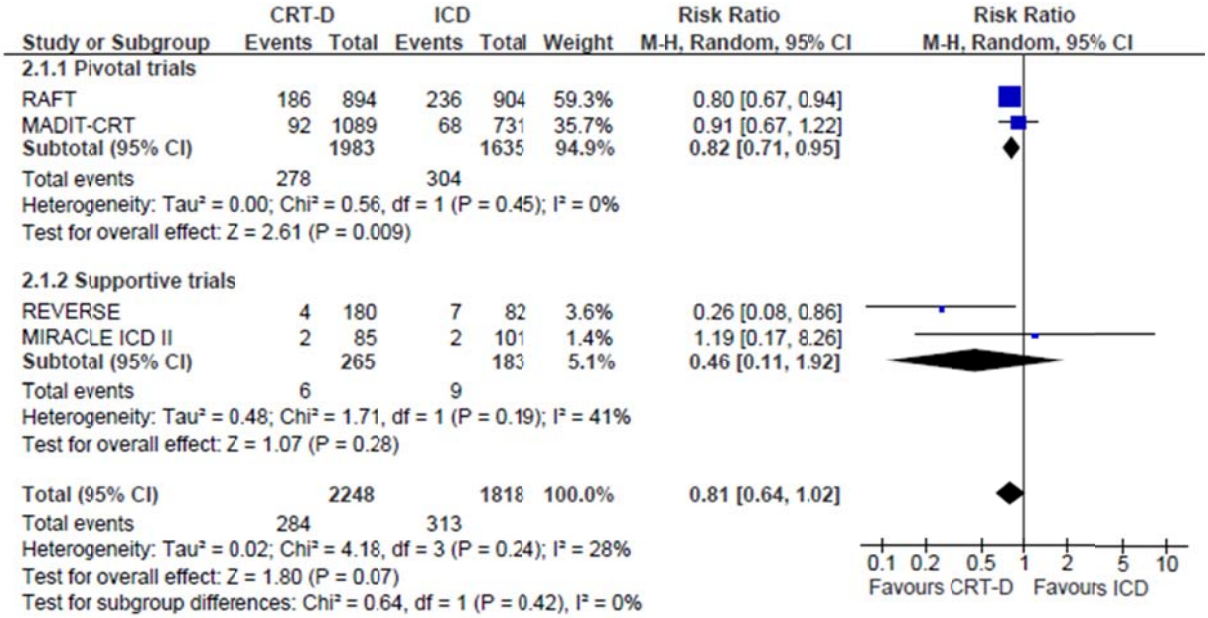
The primary evidence for the main clinical evaluation of CRT-D implantation compared with ICD implantation from two similarly designed direct comparative RCTs which showed that CRT-D implantation reduces the risk of all-cause mortality and hospitalisation for heart failure, compared with ICD implantation (Tang et al 2010[77]; Moss et a 2009[58]). Meta-analyses of the all-cause mortality, cardiovascular mortality, hospitalisation for heart failure results of these trials are shown below.

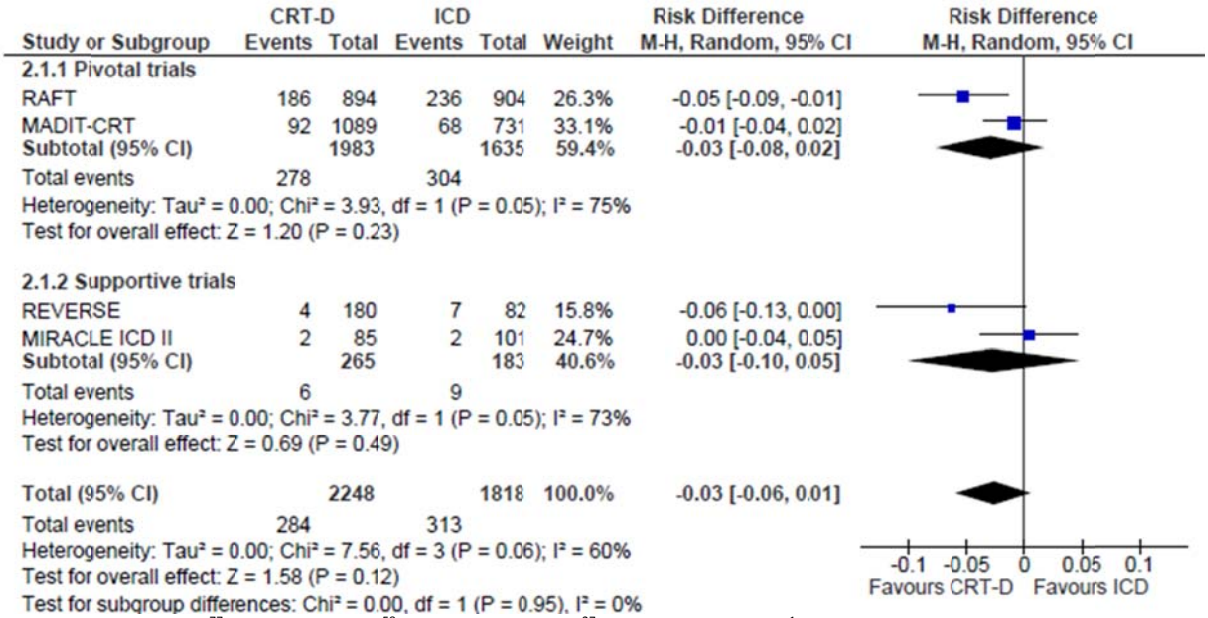
Figure B-16 Meta-analysis of all-cause mortality rates reported for RAFT and MADIT-CRT



Source: Tang et al (2010)[77], Moss et al (2009)[58]

Figure B-17 Meta-analysis of all-cause mortality rates reported for pivotal and supportive trials†

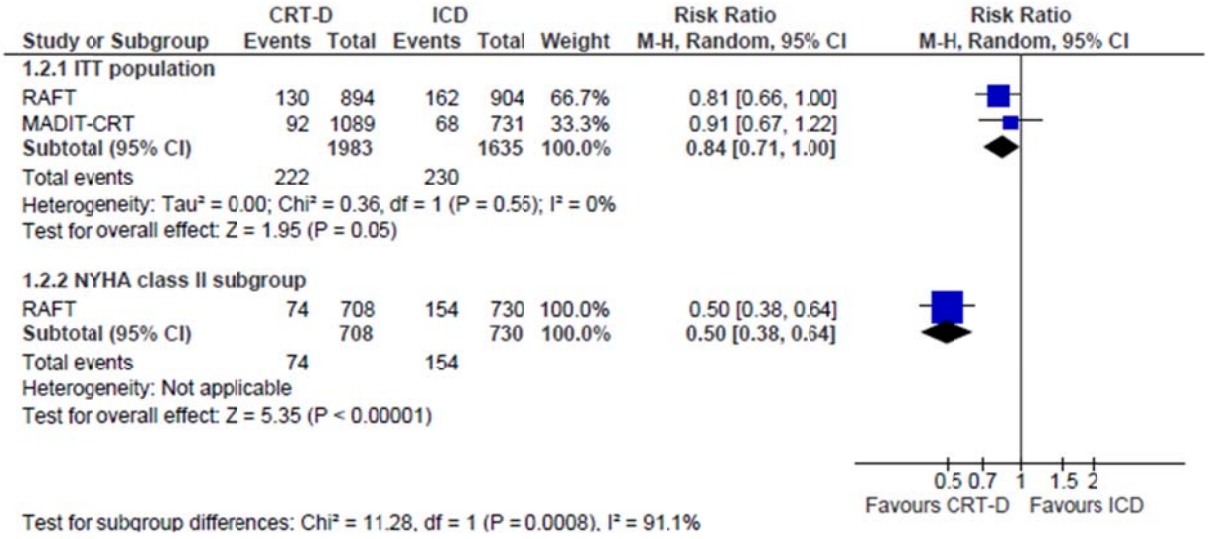


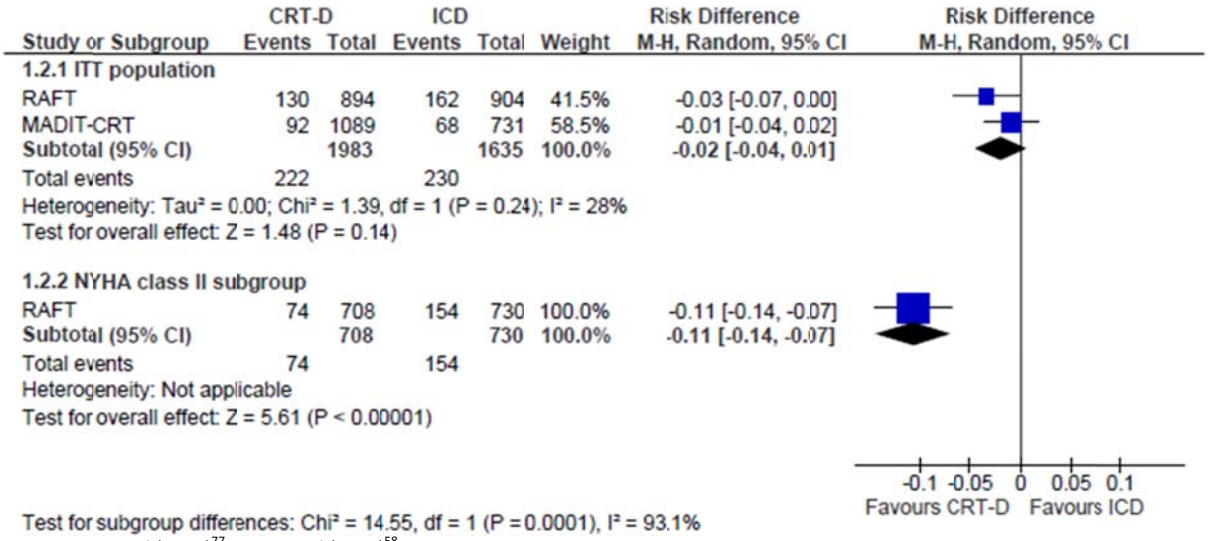


Source: Tang et al (2010)[77], Moss et al (2009)[58]; Daubert et al (2009)[27]; Abraham et al (2004)[1]

†Includes 24 month results from REVERSE European cohort

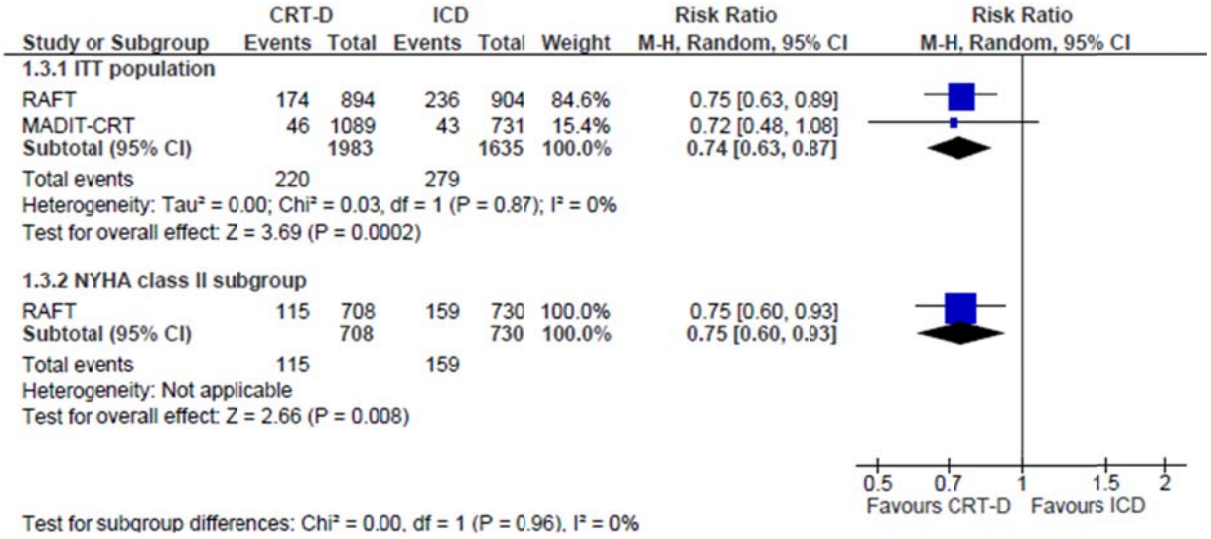
Figure B-18 Meta-analysis of cardiovascular mortality rates reported for RAFT and MADIT-CRT†

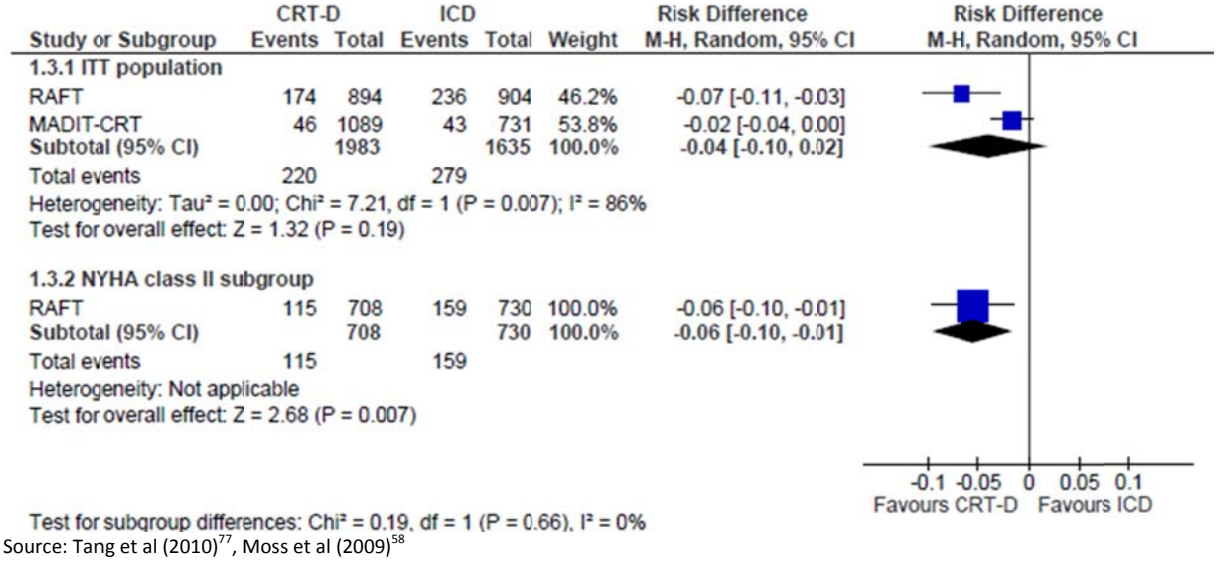




Source: Tang et al (2010)[77], Moss et al (2009)[58]
†Cardiovascular mortality not reported in supportive trials

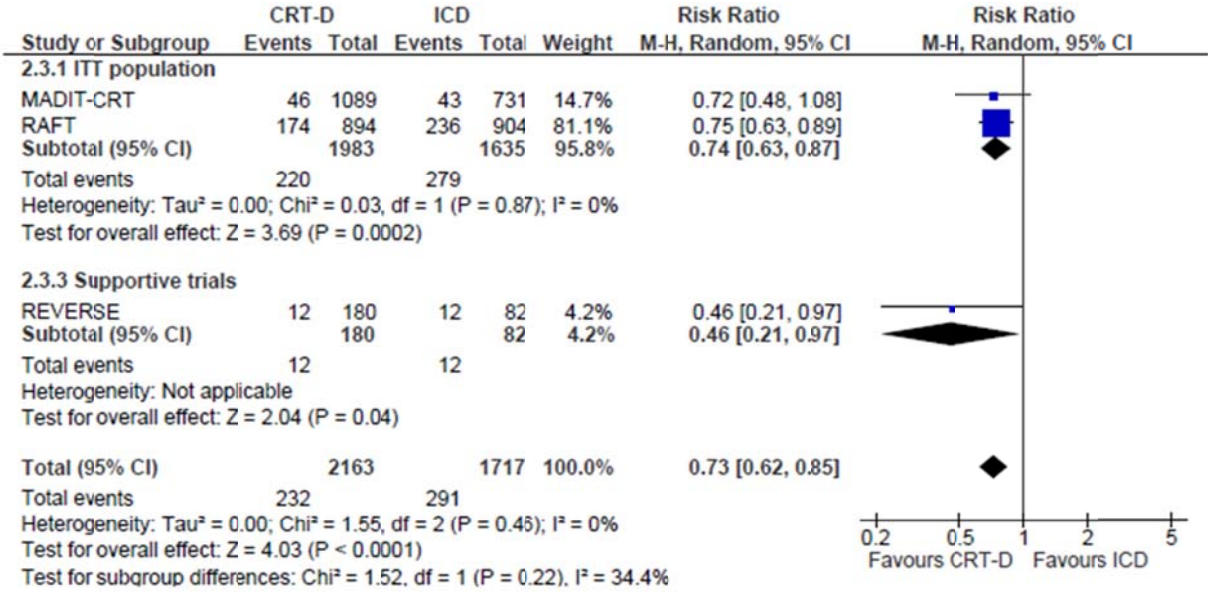
Figure B-19 Meta-analysis of hospitalisation for heart failure and heart failure event rates reported for RAFT and MADIT-CRT

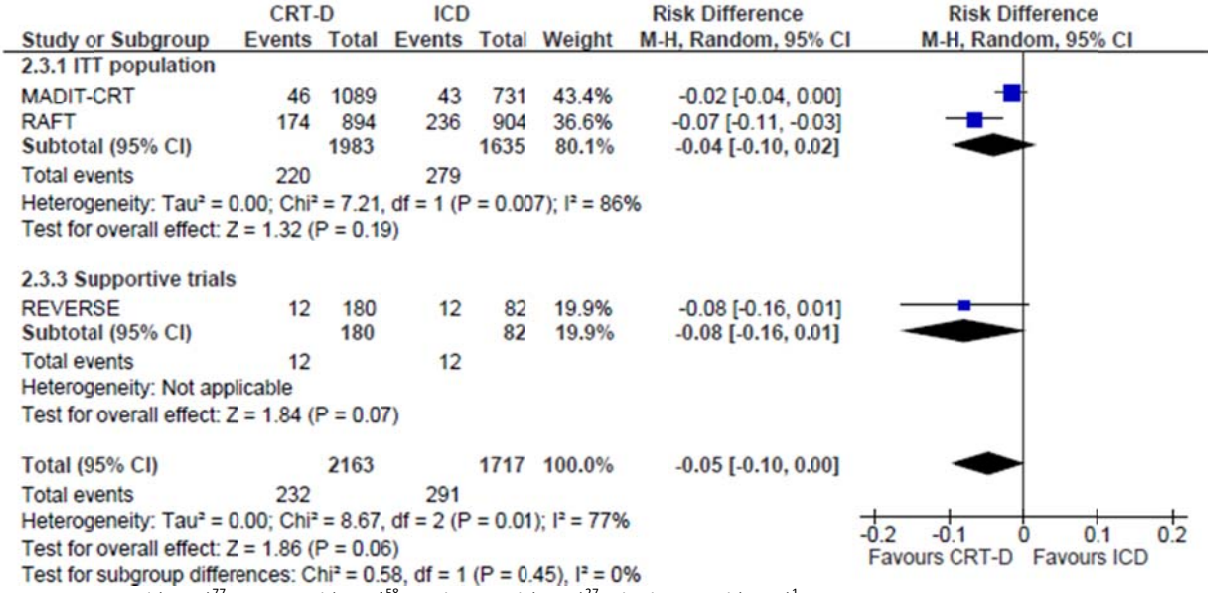




Source: Tang et al (2010)[77], Moss et al (2009)[58]

Figure B-20 Meta-analysis of hospitalisation for heart failure and heart failure event rates reported for pivotal and supportive trials†





Source: Tang et al (2010)[77], Moss et al (2009)[58]; Daubert et al (2009)[27]; Abraham et al (2004)[1]
†Not reported for MIRACLE ICD II

C SYNTHESIS WITH OTHER EVIDENCE

C.1 APPLICABILITY OF TRIAL-BASED EVIDENCE TO THE PROPOSED MBS POPULATION

Identification of issue that needs to be addressed

This application proposes the use of CRT-D as a direct substitute for ICD in patients with NYHA class II heart failure, who have sinus rhythm, an LVEF of less than or equal to 30%, and a QRS duration greater than or equal to 150 ms despite optimised medical therapy. Direct comparative trials need to be representative of this patient population and therefore of patients who would be eligible for CRT-D therapy under the proposed changes to the current MBS listings, and that the clinical outcomes observed in the pivotal trials can be expected to be replicated in an Australian context.

Focused analytic plan

In order to assess the applicability of trial-based evidence to proposed MBS population, the baseline demographic and disease characteristics of participants enrolled in the direct comparative randomised trials were compared with data sourced from an Australian analysis of current ICD use (Bradshaw et al 2013[18]), the proposed MBS criteria, and clinical recommendations made by the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand (NHFA/CSANZ 2011[59]).

Results of pre-modelling study

The study by Bradshaw et al (2013)[18] was a retrospective study of ICD use in Western Australia. It used the Health Department of Western Australia's Data Linkage System to retrospectively identify all incident cases of ICD implantation recorded between 1980 and 2009. In total, there were 1593 index admissions for ICD implantation recorded between 1988 and 2009. Patients that received an ICD implant were mostly male (82%). Those that received an ICD between 2005 and 2009 had a mean age of 63.5 years (SD, 12.6). The age and gender distribution of patients identified by Bradshaw et al[18] are consistent and comparable to the age and gender characteristics of patients enrolled in the RAFT, MADIT-CRT, REVERSE and MIRACLE ICD II trials (**Table C-1**).

Table C-1 Age and gender distribution of participants in the direct comparative randomised trials and the study by Bradshaw et al (2013)[18]

Characteristic	Pivotal trials[a]				Australian ICD recipients (Bradshaw 2013)
	RAFT		MADIT-CRT		
	CRT-D	ICD	CRT-D	ICD	
Age, years – mean (SD)	66.1 (9.3)	66.2 (9.4)	65 (11)	64 (11)	63.5 (12.6)[b]
Male sex - %	84.8%	81.0%	74.7%	75.6%	82%

Source: Tang et al (2010)[77]; Moss et al (2009)[58]; Bradshaw et al (2013)[18]

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; SD, standard deviation

a Age and distribution characteristics of participants in the direct comparative randomised trials are as presented in Table B-8.

b As reported for the period from 1988 to 2009.

Patients in the proposed MBS population are required to have NYHA class II heart failure, sinus rhythm, a LVEF of less than or equal to 30% and a QRS duration of 150 ms or more, despite optimised medical therapy. The characteristics of participants enrolled in the direct comparative randomised trials are compared against the proposed MBS criteria and the population recommended for CRT-D implantation in current Australian clinical practice guidelines (NHFA/CSANZ 2011[59]) in **Table C-2**.

Table C-2 Comparison of patients in the proposed MBS population, the populations enrolled in the pivotal trials, and the population recommended for CRT-D implantation in current Australian clinical practice guidelines

Proposed MBS population	Pivotal trials[a]		Population recommended for CRT-D in Australian clinical practice guidelines (NHFA/CSANZ 2011[59])
	RAFT	MADIT-CRT	
Patients with NYHA class II heart failure who meet all of the following criteria, despite OMT: • Sinus rhythm • LVEF ≤ 30% • QRS duration ≥ 150 ms	The RAFT trial included patients with NYHA class II or III heart failure that met all of the following criteria, despite OMT: • Sinus rhythm or permanent atrial fibrillation or flutter • LVEF ≤ 30% • Intrinsic QRS duration ≥ 120 ms or paced QRS duration ≥ 200 ms The RAFT trial included an *a priori* defined analysis by NYHA class. This provides data specific to NYHA II patients specified in the proposed MBS indication. <u>Baseline characteristics:</u> • On average, 80.0% of the trial population had NYHA class II heart failure • 87.2% had sinus rhythm[b] • 57.7% had an intrinsic QRS duration ≥ 150 ms[c]	The MADIT-CRT trial included patients with NYHA class I or II heart failure that met all of the following criteria, despite OMT: • Sinus rhythm • LVEF ≤ 30% • Intrinsic QRS duration ≥ 130 ms <u>Baseline characteristics:</u> • 85.4% of the trial population had NYHA class II heart failure • 64.6% had an intrinsic QRS duration ≥ 150 ms	Patients with NYHA class II heart failure who meet all of the following criteria, despite OMT: • LVEF ≤ 30% • QRS duration ≥ 150 ms

Source: Tang et al (2010)[77]; Moss et al (2009)[58]; NHFA/CSANZ 2011[59]

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; LVEF, left ventricular ejection fraction; MBS, Medicare Benefits Schedule; ms, milliseconds; NYHA, New York Heart Association; OMT, optimised medical therapy

a Baseline disease characteristics are as presented in Table B-8.

b Includes patients with an atrial pacemaker

c Determined from subgroup analysis, Figure 3 of Tang et al 2010[77]

Overall, the majority of patients enrolled in each trial met each of the proposed MBS criteria. The RAFT trial included patients with NYHA class II or III heart failure that had sinus rhythm or permanent atrial fibrillation or flutter, a LVEF of less than or equal to 30%, and a QRS duration of 120 ms or more or a paced QRS duration of 200 ms or more, despite optimised medical therapy. The number of participants who met all of the proposed MBS criteria could not be determined based on the available data, however 80.0% of the trial population had NYHA class II heart failure; 87.2% of all participants had sinus rhythm; and 57.7% had an intrinsic QRS duration of 150 ms or more (Tang et al 2010[77]).

The MADIT-CRT trial included patients with NYHA class I or II heart failure that had sinus rhythm, a LVEF of less than or equal to 30%, and a QRS duration of 130 ms or more, despite optimised medical therapy. The number of participants who met all of the proposed MBS criteria could not be determined, however 85.4% of trial participants had NYHA class II heart failure and 64.6% had an intrinsic QRS duration of 150 ms or more (Moss et al 2009[58]). These results indicate that the populations included in the pivotal trials for the main clinical evaluation are likely to be representative of patients in the proposed MBS population. It is therefore reasonable to assume that clinical outcomes observed in these trials are applicable to the Australian context.

The primary publication for the RAFT trial (Tang et al 2010[77]) included an *a priori* defined analysis of the efficacy of CRT-D versus ICD implantation in patients with NYHA class II heart failure who had a LVEF of less than or equal to 30% at baseline, despite optimised medical therapy (80% of total trial population; N=1438). Because this subgroup excludes patients in other NYHA classes, it matches the characteristics of the proposed MBS population more closely than the full population included in the either pivotal trial. Clinical outcomes reported for this population are used in the base case analyses presented in **Section D.**

Relationship to economic evaluation

The results of this pre-modelling study show that that baseline demographic and disease characteristics of participants enrolled in the direct comparative randomised trials are likely to be representative of patients who would receive CRT-D in Australia if the MBS listings were modified as requested. The data that most closely matches the MBS indication and the economic evaluation for CRT-D presented herein is based on the *a priori* identified efficacy results reported for the subgroup of patients with NYHA class II heart failure in the RAFT trial (Tang et al 2010[77]).

C.2 EXTRAPOLATION OF TRIAL-BASED EVIDENCE: ALL-CAUSE MORTALITY

Identification of the issue that needs to be addressed

In an *a priori* defined analysis the RAFT trial found that of the 730 NYHA Class II subjects in the ICD group, 154 (21.1%) of them died, while in the CRT-D group, 110 of 708 (15.5%) died. The adjusted hazard ratio was 0.71 in favour of CRT-D. These differences were statistically significant (p=0.006). At five years, the mortality rates were 31.0% in the NYHA Class II ICD group, and 23.7% in the NYHA Class II CRT-D group. While these results show that CRT-D has a survival benefit when compared to ICD treatment (in NHYA II patients over the trial period), a large proportion of patients in both arms of the trial remain alive at the end of follow-up (see **Figure C-1**). Therefore, any mean estimation of survival benefit generated over the trial period is truncated and will not reflect the true magnitude of survival benefit a population can expect from the introduction of CRT-D treatment over their lifetime. Consequently, a method of extrapolating the survival benefits beyond the trial period was required.

Focused analytic plan

As the individual patient data (IPD) were not available to the Sponsors (the RAFT trial was an investigator initiated RCT conducted by a third-party) the Kaplan Meier survival curves comparing ICD and CRT-D needed to be reproduced manually from images presented in the RAFT publication (Figure 2C; Tang et al 2010[77]). One of the most commonly used parametric survival functions applied in the economic modelling of health care (ie. Weibull distribution) was then fitted to the ICD survival curve (by ordinary least squares; OLS) to ascertain a baseline hazard associated with this treatment. To ensure any minor baseline imbalances between arms were accounted for the adjusted hazard ratio

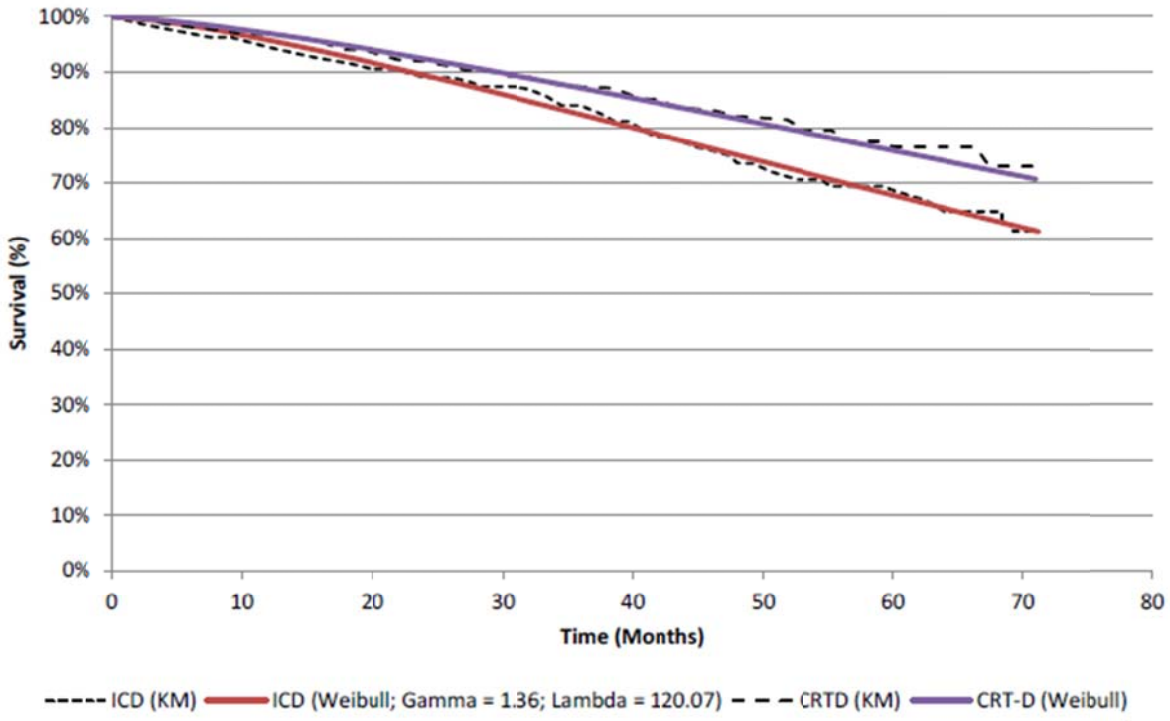
(0.71) was then applied to the baseline Weibull hazard function to determine the treatment effect due to CRT-D treatment over time. A secondary analysis was also conducted assuming that hazards were constant over time (ie. using an exponential survival function). The results of this analysis are presented in the sensitivity analyses presented in **Section D.6**.

Results of the pre-modelling study

A comparison of the non-parametric Kaplan Meier survival curves and the parametric Weibull analysis for both treatment arms over the trial period are presented in **Figure C-1**.The figure also presents the gamma (1.36) and lambda (120.07) parameter values estimated by OLS. The survival functions are compared over the cohort's lifetime in **Figure C-2**.

Using the Weibull survival function the survival associated with ICD and CRT-D could then be projected beyond the trial period to determine the survival benefits that CRT-D can be expected to bring over the lifetime of the treated cohort. As assumed in the MSAC review of ICDs conducted in 2006 (see *MSAC Reference 32 p. 140 and Appendix G*), and due to the chronic nature of the treatment the adjusted hazard ratio favouring CRT-D over ICD was assumed to be maintained over the time horizon of the economic model. This assumption was tested in sensitivity analyses (see **Section D.6**).

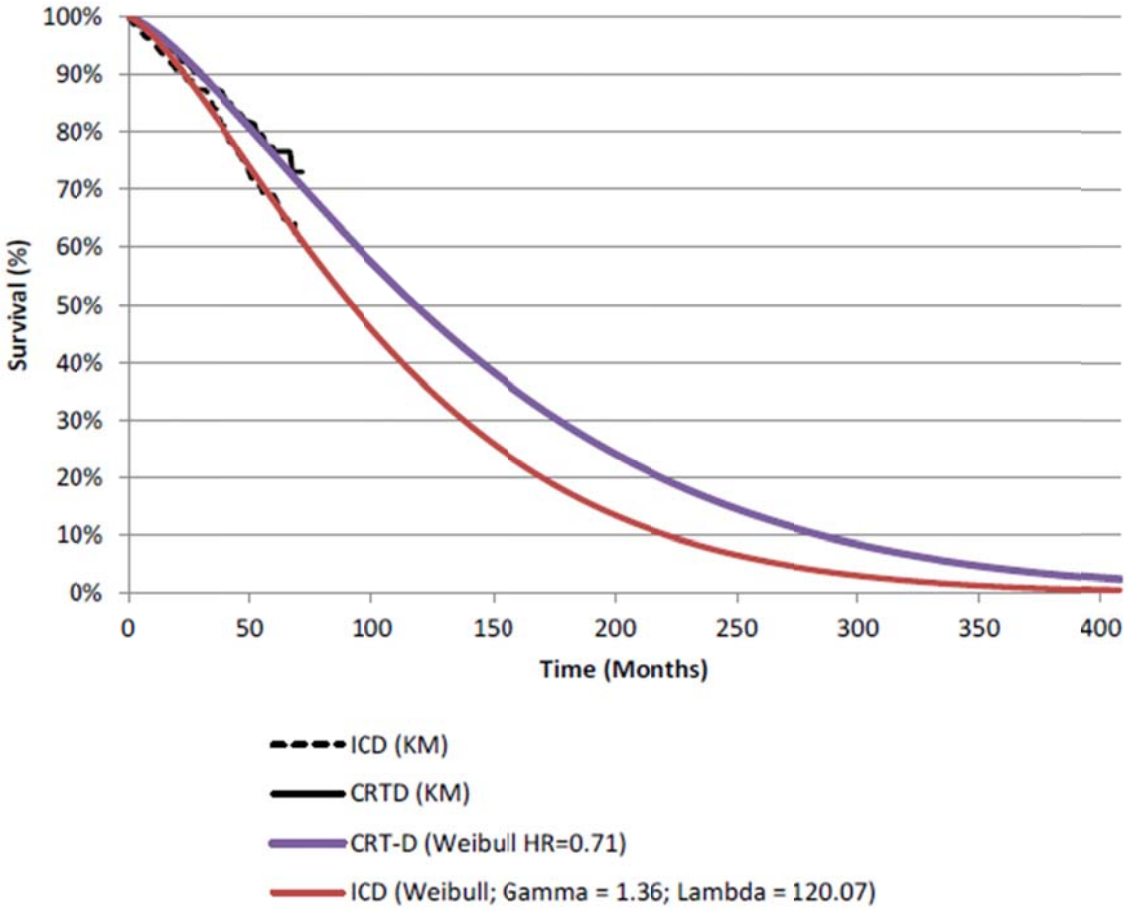
Figure C-1 Comparison of Kaplan Meier and Weibull survival analysis for patients with NYHA class II heart failure



Source: Figure 2C Tang et al (2010)[77]

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, Implantable cardioverter defibrillator; KM, Kaplan Meier

Figure C-2: Comparison of Kaplan Meier and Weibull survival analysis for patients with NYHA class II heart failure (life-time)



Relationship to the economic evaluation

The results of this pre-modelling study show that a Weibull function (Gamma = 1.36 and Lambda 120.07) accurately represents the survival of patients treated with an ICD in the RAFT trial. After application of the adjusted hazard ratio favouring CRT-D over ICD (0.71; 95% CI, 0.56-0.91, *p*=0.006) to the baseline hazard (ie. ICD hazard) the survival benefit expected with CRT-D is also accurately represented. This provides a basis on which to extrapolate treatment effect beyond the trial period in the economic model presented in **Section D**.

C.3 UTILITY WEIGHT ESTIMATES

Identification of issue that needs to be addressed

The EQ-5D results of the MADIT-CRT trial showed that patients with NYHA class I or II heart failure that underwent CRT-D implantation had significantly improved health-related quality of life, compared to those who underwent ICD implantation, over a mean follow-up duration of 28 months. These results are directly applicable to the proposed MBS population, but have also been compared with utility values sourced from the literature.

Focused analytic plan

A comprehensive literature search was conducted to identify preference-based utility weights applicable to the proposed MBS population. This search specifically aimed to identify publications that described preference-based utility weight estimates that were applicable to patients with chronic heart failure, were applicable to adverse outcomes (e.g. hospitalisation for heart failure), or were representative of differing levels of CRT-D or ICD treatment response. Details of the literature search methodology are presented in **Appendix D.**

Results of pre-modelling study

In total, the literature search for relevant utility weight estimates identified 34 publications that reported preference-based utility weight estimates that related to chronic heart failure. The characteristics and results of these studies are presented in **Appendix D**.

Ten studies (including the MADIT-CRT trial) reported utility weight estimates that are applicable to patients with mild chronic heart failure (NYHA I-II). These are summarised below in **Table C-3**. The mean baseline utility of participants in the CRT-D arm of the MADIT-CRT trial was 0.848 (SD, 0.134) and the mean baseline utility of participants in the ICD arm was 0.845 (SD, 0.134) (Noyes et al 2013[63]). These utility weight estimates appear high when compared with published estimates of the utility of patients with mild chronic heart failure (range, 0.64 to 0.82; Alehagen et al 2008[4]; Cleland et al 2008[26]; Ford et al 2012[30]; Gohler et al 2009[31]; Havranek et al 2004[37]; Linde et al 2011[51]; Miller et al 2009[56]; Pradelli et al 2009[67]; Yao et al 2007[82]). This can partially be explained by the fact that 14.6% of participants in the MADIT-CRT trial had NYHA class I heart failure, and were therefore asymptomatic at baseline. Patients with NYHA class I heart failure are asymptomatic (despite left ventricular dysfunction), and have a higher quality of life than those with NYHA class II heart failure (Yao et al 2007[82]. The use of utility values sourced directly from the MADIT-CRT trial may potentially underestimate the quality of life benefit associated with use of CRT-D in the proposed patient population as these patients may have less impairement at baseline and, therefore, may have less room for utility improvement with CRT-D. A weighted average baseline utility estimate was calculated to account for differences in the mean baseline utility of participants in each arm of the MADIT-CRT trial.

Table C-3 Utility weight estimates applicable to mild chronic heart failure

Study ID	Country	Study description	Method of elicitation	Relevant health state	Utility
Trial-based utilities					
MADIT-CRT (Noyes 2013[63])	US, Europe and Canada	Trial-based evaluation of MADIT-CRT (NYHA I/II)	EQ-5D Elicited directly from patients in health state	Baseline utility: • CRT-D • ICD **Weighted average**	 0.848 (SD 0.134) 0.845 (SD 0.134) **0.847**
Supportive studies					
Alehagen 2008[4]	Sweden	HRQoL study assessing utility weights among elderly patients with chronic heart failure (NYHA I-III)	TTO Elicited directly from patients in health state	NYHA class II heart failure	0.71 (95% CI 0.66, 0.74)
Cleland 2008[26]	International	Long-term follow-up of a RCT comparing CRT-P with OMT for the heart failure, CARE-HF (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	Mean utility of patients with NYHA I or II heart failure at baseline	0.78 (95% CI 0.69, 0.85)
Ford 2012[30]	Australia	CUA comparing hawthorne extract to standard care for the treatment of heart failure (NYHA I-IV)	Estimated from the literature (Yao 2007)	NYHA class II heart failure (no hospitalisation)	0.72
Gohler 2009[31]	Germany	HRQoL substudy of RCT comparing administration of eplerenone to patients with heart failure after acute MI, versus standard care (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	NYHA class II heart failure	0.714
Havranek 2004[37]	US/Canada	HRQoL substudy of RCT comparing omapatrilat to eplerenone in patients with chronic heart failure (NYHA II-IV)	TTO Elicited directly from patients in health state	NYHA class II heart failure	0.82 (SD 0.25)
Linde 2011[51]	UK	CUA based on the REVERSE trial (NYHA I/II)	Estimated from the literature	NYHA class II heart failure	0.78 (95% CI 0.72, 0.84)
Miller 2009[56]	US	CUA of the long-term impact of a heart failure management programme (NYHA I-IV)	Estimated from SF-36 scores	NYHA class II heart failure	0.64
Pradelli 2009[67]	Italy	CUA of valsartan for the treatment of chronic heart failure (NYHA II-IV)	Estimated from the literature	NYHA class II heart failure	0.813
Yao 2007[82]	UK	Trial-based CUA comparing CRT-D with CRT-P (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	NYHA class II heart failure	0.720 (95% CI 0.72, 0.69)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; CRT-P, cardiac resynchronisation therapy pacemaker; CUA, cost-utility analysis; EQ-5D, EuroQol-5 Dimensions; HRQoL, health-related quality of life; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; OMT, optimised medical therapy; SF-36, Short Form 36 Health Survey; TTO, time-trade-off

Source: Noyes et al (2013)[63], Alehagen et al (2008)[4], Cleland et al (2008)[26], Ford et al (2012)[30], Gohler et al (2009)[31], Havranek et al (2004)[37], Linde et al (2011)[51], Pradelli et al (2009)[67], Yao et al (2007)[82]

Seven studies (including the MADIT-CRT trial) reported estimates of changes in health-related quality of life associated with CRT-D or ICD implantation in patients with NYHA class II heart failure. In the MADIT-CRT trial, participants that received a CRT-D had a mean utility of 0.884 (SD 0.145) over 28 months of follow-up, compared with 0.874 (SD, 0.145) for participants that received an ICD. In both groups this represented a small but significant improvement in health-related quality of life from baseline (P-value not reported). The difference between treatment groups was reported to be statistically significant (Noyes et al 2013[63]). The magnitude of change in quality of life reported for both arms of the MADIT-CRT is consistent with other published estimates of changes in health-related quality of life associated with CRT-D and ICD implantation (Chen et al 2004[23]; Feldman et al 2005[29]; Noyes et al 2009[62]; Ozasa et al 2008[64]; Riberio et al 2010[70]; Sanders et al 2010[72]).

Table C-4 Utility weight estimates before and after device therapy for heart failure

Study ID	Country	Study description	Method of elicitation	Relevant health state	Utility
Trial-based utilities					
MADIT-CRT (Noyes 2013[63])	US, Europe and Canada	Trial-based evaluation of MADIT-CRT (NYHA I/II)	EQ-5D Elicited directly from patients in health state	CRT-D: • Baseline • During follow-up • During follow-up adjusted for minor baseline differences ICD • Baseline • During follow-up • During follow-up adjusted for minor baseline differences	 0.848 (SD 0.134) 0.884 (SD 0.145) 0.883[a] 0.845 (SD 0.134) 0.874 (SD 0.145) 0.876[a]
Supportive studies					
Chen 2004[23]	US	CUA of ICD for primary prevention of sudden cardiac death in patients with congestive heart failure	Assumptions based on literature	Patients with congestive heart failure: • Baseline • One year after ICD implant • Two years after ICD implant	0.71 0.71 0.639 0.71
Feldman 2005[29]	International	RCT and CUA comparing CRT-D with CRT-P and OMT for the treatment of moderate to severe heart failure (NYHA III-IV)	Mapped from MLWHFQ scores elicited from patients in health state	CRT-D: • Baseline • 3 months • 6 months CRT-P: • Baseline • 3 months • 6 months	 0.62 0.77 0.77 0.62 0.78 0.79
Noyes 2009[62]	US	CUA of ICD versus OMT for patients with chronic heart failure from the MADIT II trial (NYHA I-IV)	HUI3 Elicited directly from patients in health state	ICD: • Baseline • During follow-up OMT: • Baseline • During follow-up	 0.637 0.601 0.646 0.678
Ozasa 2008[64]	Japan	CUA of ICD	TTO	ICD:	

Study ID	Country	Study description	Method of elicitation	Relevant health state	Utility
		implantation in patients with chronic heart failure	Questionnaire administered to 27 cardiologists	• Well • Complication	0.792 0.589
Riberio 2010[70]	Brazil	CUA of ICD implantation in patients with heart failure (NYHA II or III)	Estimated from the literature	ICD: • Baseline • During follow-up	 0.88 0.88
Sanders 2010[72]	US	CUA of ICD implantation in patients aged 65 years or more with chronic heart failure	Estimated from the literature	ICD: • Baseline • During follow-up	 0.88 0.88

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; CRT-P, cardiac resynchronisation therapy pacemaker; CUA, cost-utility analysis; EQ-5D, EuroQol-5 Dimensions; HUI3, health utilities index version 3; ICD, implantable cardioverter defibrillator; MLWHFQ, Minnesota Living with Heart Failure questionnaire; NYHA, New York Heart Association; OMT, optimised medical therapy; RCT, randomised controlled trial; SF-36, Short Form 36 Health Survey; TTO, time-trade-off
Source: Noyes et al (2013)[63], Chen et al (2004)[23], Feldman et al (2005)[29], Noyes et al (2009)[62], Ozasa et al (2008)[64], Riberio et al (2010)[70], Sanders et al (2010)[72]
[a] See *CRTD Supportive calculations workbook.xls* for calculation details

Relationship to economic evaluation

The base case economic evaluation presented in **Section D** uses preference-based health-related quality of life (utility) weight estimates sourced from the MADIT-CRT trial (Noyes et al 2013[63]). These values appear to be consistent with those reported in other studies that have assessed preference-based quality of life in patients with mild chronic heart failure. As these values are collected in a head-to-head RCT comparison of the two treatments of interest (ICD and CRT-D) they capture any utility improvements or disutility associated with the two treatments. As such, these utility weights are applied to the appropriate arm of the economic model without application of different utility weights to different health states. These estimates are subjected to a range of sensitivity analyses presented in Section D.6 of this submission. A supplementary analysis in which all preference-based health-related quality of life weighting of survival is removed (ie. a cost per life-year-saved analysis) is presented in Section D.5 of this submission).

C.4 COST OF OPTIMISED MEDICAL THERAPY

Identification of issue that needs to be addressed

All patients who receive a CRT-D or ICD implant continue to receive optimised medical therapy. It was necessary to estimate an indicative cost of optimised medical therapy for use in the economic evaluation presented in **Section D**.

Focused analytic plan

The methodology described in MSAC Assessment Report 32 was used to estimate the annual cost of optimised medical therapy for chronic heart failure in Australia. To ensure that all underlying assumptions appropriately reflect current clinical practice, this included:

- A review of the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand's recommendations for pharmacologic treatment of symptomatic chronic heart failure (NHFA/CSANZ 2011[59])
- A focused literature search that aimed to identify studies that characterised the types of drugs that would typically be used to manage patients with NYHA class II heart failure in current clinical practice
- The development of a typical treatment plan for the management of chronic heart failure in patients who meet the proposed MBS criteria
- The calculation of an indicative annual cost of optimised medical therapy based on data sourced from the Pharmaceutical Benefits Schedule (PBS)

Results of the pre-modelling study

Table C-5 summarises the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand's recommendations for pharmacologic treatment of symptomatic chronic heart failure. ACE inhibitors and beta-blockers are recommended for all patients with systolic heart failure (LVEF < 40%), unless contraindicated or not tolerated. Diuretics should be used as necessary to provide symptomatic relief. Other recommended agents include aldosterone antagonists, angiotensin II receptor antagonists, digoxin, calcium channel blockers and direct sinus node inhibitors (NHFA/CSANZ 2011[59]).

Two prospective observational studies were identified that sought to characterise the types of drugs that would typically be used to manage patients with heart failure. Both were designed to assess the relative proportions of patients receiving different types of treatment in clinical practice, however neither study stratified medication use by NYHA class (Heywood et al 2010[40]; Atwater 2012[8]).

Heywood et al (2010)[40] compared rates of medication use among patients with and without cardiac device implants in the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF) study. This analysis was based on the medical records of 15,381 patients receiving care at 167 outpatient cardiology practices in the US. Patients with CRT-D, CRT-P and ICD implants were found to receive evidence-based medical therapy at similar or greater frequency than did those without such devices. Patients with CRT-D and ICD implants had similar rates of ACE inhibitor of angiotensin II antagonist, beta-blocker and aldosterone antagonist use.

Atwater et al (2010)[8] assessed rates of guideline adherence and medication use among 178 patients with a primary or secondary diagnosis of chronic heart failure. After accounting for medical contraindications, it was found that 72% of patients adhered to guideline-recommended therapy, and that patients with NYHA class I or II heart failure had higher overall rates of adherence than those with NYHA class III or IV disease.

The relative proportions of patients receiving different types of medication in the studies by Heywood et al (2010)[40] and Atwater (2010)[8] appear to be consistent with rates of medication use in the RAFT and MADIT-CRT trials, and are broadly comparable with typical treatment plan for the management of chronic heart failure developed for use in MSAC Assessment Report 32 (**Table C-5**). It is therefore reasonable to apply the same underlying assumptions about medication use to estimate an indicative cost of optimised medical therapy for use in the economic evaluation. These calculations are shown in **Table C-6**.

Table C-5 Summary of the National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand's recommendations for pharmacologic treatment of symptomatic chronic heart failure and assumptions relating to optimised medical therapy

Australian clinical practice guidelines for management of symptomatic chronic heart failure (Grade of recommendation)	Proportion of patients receiving therapy (%)						Estimated proportion of patients receiving therapy in base case economic evaluation (%)	Assumptions applied in the base case economic evaluation
	Pivotal trials[a]		IMPROVE HF		Atwater 2012[8]	MSAC Assessment Report 32[54]		
	RAFT	MADIT-CRT	CRT-D	ICD				
ACE inhibitors • Unless not tolerated or contraindicated, ACE inhibitors are recommended for all patients with systolic heart failure (LVEF < 40%), whether symptoms are mild, moderate or severe (A) • Every effort should be made to increase doses of ACE inhibitors to those shown to be of benefit in major trials. If this is not possible, a lower dose of is preferable to none at all (B)	NR 96% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	77%	NR 79.3% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	NR 81.6% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	NR 95% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	90%	90%	The indicative cost of OMT is based on the cost of ramipril at an average daily dose of 5 mg (consistent with MSAC Assessment Report 32[54]).
Diuretics • Diuretics should be used, if necessary, to achieve euvolaemia in fluid-overloaded patients. In patients with systolic LV dysfunction, diuretics should never be used as monotherapy, but should always be combined with an ACE inhibitor to maintain euvolaemia (D)	84%	75%	NR	NR	NR	100%	100%	It is assumed that all patients in the proposed MBS population will receive a diuretic for symptomatic relief of fluid overload. The indicative cost of OMT is based on the cost of frusemide at an average daily dose of 80 mg (consistent with MSAC Assessment Report 32[54]). Because 10-15% of patients may take frusemide intermittently, the average daily dose has been adjusted to 70% (56mg) for 15% of patients (consistent with MSAC Assessment Report 32[54]).

Australian clinical practice guidelines for management of symptomatic chronic heart failure (Grade of recommendation)	Proportion of patients receiving therapy (%)						Estimated proportion of patients receiving therapy in base case economic evaluation (%)	Assumptions applied in the base case economic evaluation
	Pivotal trials[a]		IMPROVE HF		Atwater 2012[8]	MSAC Assessment Report 32[54]		
	RAFT	MADIT-CRT	CRT-D	ICD				
Beta-blockers • Unless not tolerated or contraindicated, beta-blockers are recommended, for all patients with systolic heart failure who remain mildly to moderately symptomatic despite appropriate doses of an ACE inhibitor(A) • Beta-blockers are also indicated for patients with symptoms of advanced heart failure (B)	90%	93%	88.9%	88.5%	98%	90%	90%	The indicative cost of OMT is based on the cost of carvedilol at a n average daily dose of 25 mg (consistent with MSAC Assessment Report 32[54]).
Aldosterone antagonists • Aldosterone receptor blockade with spironolactone is recommended for patients who remain severely symptomatic, despite appropriate doses of ACE inhibitors and diuretics (B) • Aldosterone blockade with eplerenone should be considered in systolic heart failure patients who still have mild (NYHA Class II) symptoms despite receiving standard therapies (ACE inhibitor, beta-blocker) (B)	14%	7%	39.7%	37.9%	51%	30%	30%	It is assumed that 30% of patients in the proposed MBS population will receive treatment with an aldosterone antagonist for consistency with MSAC Assessment Report 32[54]. The indicative cost of OMT is based on the cost of spironolactone at an average daily dose of 25 mg (consistent with MSAC Assessment Report 32[54]. The cost of eplerenone has not been used as eplerenone is currently not TGA approved or PBS listed for this indication.

Australian clinical practice guidelines for management of symptomatic chronic heart failure (Grade of recommendation)	Proportion of patients receiving therapy (%)						Estimated proportion of patients receiving therapy in base case economic evaluation (%)	Assumptions applied in the base case economic evaluation
	Pivotal trials[a]		IMPROVE HF		Atwater 2012[8]	MSAC Assessment Report 32[54]		
	RAFT	MADIT-CRT	CRT-D	ICD				
Angiotensin II receptor antagonists • Angiotensin II receptor antagonists may be used as an alternative in patients who do not tolerate ACE inhibitors due to kinin-mediated adverse effects (e.g. cough). They should also be considered for reducing morbidity and mortality in patients with systolic CHF who remain symptomatic despite receiving ACE inhibitors (A)	NR 96% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	20%	NR 79.3% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	NR 81.6% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	NR 95% of all participants were on an ACE inhibitor or angiotensin II receptor antagonist	10%	10%	The indicative cost of OMT is based on the cost of irbesartan at an average daily dose of 150 mg (consistent with MSAC Assessment Report 32[54]).
Direct sinus node inhibitors • Direct sinus node inhibition with ivabradine should be considered for heart failure patients with impaired systolic function and a recent heart failure hospitalisation who are in sinus rhythm where their heart rate remains > 70 bpm despite efforts to maximise dosage of background beta-blockade (B)	NR	NR	NR	NR	NR	0%	0%	It is assumed that no patients in the proposed MBS population will receive treatment with ivadrabine in clinical practice as this has not yet been TGA approved or PBS listed.
Digoxin • Digoxin may be considered for symptom relief and to reduce hospitalisation in patients with advanced chronic heart failure. It remains a valuable therapy in heart failure patients with atrial fibrillation (B)	34%	25%	NR	NR	NR	20%	20%	The indicative cost of OMT is based on the cost of digoxin at an average daily dose of 125 mg (consistent with MSAC Assessment Report 32[54]).

Australian clinical practice guidelines for management of symptomatic chronic heart failure (Grade of recommendation)	Proportion of patients receiving therapy (%)						Estimated proportion of patients receiving therapy in base case economic evaluation (%)	Assumptions applied in the base case economic evaluation
	Pivotal trials[a]		IMPROVE HF		Atwater 2012[8]	MSAC Assessment Report 32[54]		
	RAFT	MADIT-CRT	CRT-D	ICD				
Calcium channel blockers • Calcium channel blockers (amlodipine and felodipine) can be used to treat comorbidities such as hypertension and coronary heart disease in patients with systolic heart failure. They have been shown to neither increase nor decrease mortality (B)	10%	NR	NR	NR	NR	10%	10%	The indicative cost of OMT is based on the cost of amlodipine at an average daily dose of 5 mg (consistent with MSAC Assessment Report 32[54]).
Other agents • Hydralazine-isosorbide dinitrate combination should be reserved for patients who are truly intolerant of ACE inhibitors and angiotensin II receptor antagonists, or for whom these agents are contraindicated and no other therapeutic option exists (B) • Fish oil (n-3 polyunsaturated fatty acids) should be considered as a second-line agent for heart failure patients who remain symptomatic despite standard therapy which should include ACE inhibitors or aldosterone antagonists and beta-blockers if tolerated (B) • Iron deficiency should be looked for and treated in heart failure patients to improve symptoms, exercise tolerance and quality of life (B)	NR	NR	NR	NR	NR	NR	0%	

Abbreviations: ACE, angiotensin-converting-enzyme; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; HF, heart failure; ICD, implantable cardioverter defibrillator; LV, left ventricular; LVEF, left ventricular ejection fraction; MBS, Medicare Benefits Scheme; MSAC, Medical Services Advisory Committee; New York Heart Association; NR, not reported; OMT, optimised medical therapy; TGA, Therapeutic Goods Administration

Source: Tang et al (2010)[77], Moss et al (2009)[58], Haywood et al (2010), Atwater et al (2012); MSAC Assessment Report 32

a As presented in Table B-8

Table C-6 Estimated cost of optimised medical therapy

Drug type	Assumptions applied in base case evaluation[a, b]		PBS data				Calculated estimates[c]	
	Estimated proportion of patients receiving therapy (%)	Estimated average daily dose (mg)	PBS code	Product, dose and form	Max qty	DPMQ	Estimated cost per day	Estimated annual cost
ACE inhibitors	90%	5 mg	1946K	Ramipril, 5 mg tablet	30	$12.17	$148.07	$133.26
Loop diuretics[d]	85%	80 mg	2412Y	Frusemide, 40 mg tablet	100	$8.42	$61.47	$52.25
	15%	56 mg	2412Y	Frusemide, 40 mg tablet	100	$8.42	$43.03	$6.45
Beta-blockers	90%	25 mg	8258P	Carvedilol, 25 mg tablet	60	$52.10	$316.94	$285.25
Aldosterone antagonists	30%	25 mg	2339D	Spironolactone, 25 mg tablet	100	$12.29	$44.86	$13.46
Angiotensin II receptor antagonists	10%	150 mg	8247C	Irbesartan, 150 mg tablet	30	$16.17	$196.74	$19.67
Digoxin	20%	125 µg	2605D	Digoxin, 62.5 µg tablet	200	$10.52	$38.40	$7.68
Calcium channel blockers	10%	5 mg	2751T	Amlodipine, 5 mg tablet	30	$9.53	$115.95	$11.59
Estimated annual cost of optimised medical therapy								**$529.61**

Abbreviations: ACE, Angiotensin-converting enzyme; DPMQ, dispensed price per maximum quantity; PBS, Pharmaceutical Benefits Schedule; MSAC Assessment Report 32[54]

Source: MSAC Assessment Report 32[54], Table 38; Pharmaceutical Benefits Schedule, 1 May 2013[10]

a All drug types, probabilities, and doses are based on expert opinion as reported MSAC Assessment Report 32. Costs are estimates only as patients may choose to purchase drugs in different formats, which would cause costs to vary slightly. Estimates are based on dosages of tablets being as close as possible to the daily dosage and on minimum listed prices.

b As shown in **Table C-5 .**

c See <CRT-D model inputs.xls> for detailed calculations . Estimated annual cost = Estimated cost per day * 365 days * probability.

d The indicative cost of OMT is based on the cost of frusemide at an average daily dose of 80 mg. MSAC Assessment Report 32 states that 10 to 15% of patients may take frusemide intermittently. The average daily dose of frusemide is adjusted to 70% (56mg) for 15% of patients to account for this.

Relationship to the economic evaluation

The annual cost of optimised medical therapy has been estimated using the methodology described in MSAC Assessment Report 32[54]. This estimate is based on a series of assumptions that are consistent with current Australian clinical practice guidelines, the pivotal RCTs, and prospective observational studies that sought to characterise the types of drugs that would typically be used to manage patients with heart failure in current clinical practice. The annual cost of optimised medical therapy applied as an input in the economic model is identical in both arms. However, since patients survive longer in the CRT-D arm of the economic model total costs of OMT accrued over the modelling period will be slightly higher for this arm of the economic model. It is likely that this is a conservative approach given that CRT-D may reduce the need for OMT compared to ICD.

C.5 SUMMARY OF THE PRE-MODELLING STUDIES AND THEIR APPLICATION IN THE ECONOMIC MODEL

Table C-7 presents a summary of the findings of the pre-modelling studies and their application in the economic evaluation presented in **Section D**.

Table C-7 Summary of the findings of the pre-modelling studies and their application to the economic evaluation

Description of pre-modelling issue	Section C cross-reference	Findings	Values used in the economic analysis	Section D cross-reference
Applicability of the trial based evidence to the proposed MBS indication and the economic analysis	Section C.1	The population that most closely matches the MBS indication sought for CRT-D and the economic evaluation presented herein was presented in the *a priori* identified NYHA II subgroup of the RAFT trial (Tang et al 2010[77])	Where available, data from the NYHA II *a priori* identified subgroup of patients in the RAFT trial were used to populate the economic model	**Section D.1-D.6** Step 1a, 1b, 1c, 2 and 3
Extrapolation of trial based evidence for all-cause mortality	Section C.2	A Weibull function accurately represents the survival of patients treated with an ICD in the RAFT trial. After application of the adjusted hazard ratio favouring CRT-D over ICD (0.71; 95% CI, 0.56-0.91, *p*=0.006) to the baseline hazard (ICD hazard) the survival benefit expected with CRT-D is also accurately represented.	A Weibull function (Gamma = 1.36 and Lambda 120.07) is used to represent the baseline hazard (ICD arm) of all-cause mortality in the economic model. The CRT-D all-cause mortality estimates are estimated by application of the adjusted HR (0.71) to the baseline hazard.	**Section D.1-D.6** Step 1b, 1c, 2 and 3
			An alternative model (exponential) is also fitted to the survival data to ascertain the impact this has on the incremental cost-effectiveness of CRT-D compared to ICD	**Section D.6** (Sensitivity analyses)
Preference-based health-related quality of life (utility estimates)	Section C.3	Utility weight estimates sourced directly from the MADIT-CRT RCT trial (Noyes et al 2013[63]) appear consistent with those reported in other studies that have assessed utility weights in patients with mild chronic heart failure. As these utility weights are derived directly from an RCT comparing the treatments of interest	Baseline utility applied for first 6 months of economic model in both ICD and CRTD arms = 0.847 Utility weight applied to ICD arm from > 6 months = 0.876 Utility weight applied to CRT-D arm from > 6 months = 0.883	**Section D.1-D.6** Step 1c, 2 and 3

Description of pre-modelling issue	Section C cross-reference	Findings	Values used in the economic analysis	Section D cross-reference
		they are simply applied directly to each arm of the economic model.		
			A supplementary analysis in which all preference-based health-related quality of life weighting of survival is removed (ie. a cost per life-year-saved analysis) is also conducted.	Supplementary analysis 1 Section D.5
Cost of optimised medical therapy	Section C.4	The annual cost of optimised medical therapy has been estimated using the methodology described in MSAC Assessment Report 32[54].	Annual cost of OMT applied to both arms of the economic model = $529.61	**Section D.1-D.6** Step 1a, 1b, 1c, 2 and 3

Abbreviations: ACE, Angiotensin-converting enzyme; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; HR, hazard ratio; ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Scheme; MSAC, Medical Services Advisory Committee; OMT, optimised medical therapy; RCT, randomised controlled trial

D ECONOMIC EVALUATION FOR THE MAIN INDICATION

D.1 OVERVIEW OF THE ECONOMIC EVALUATION

The current application proposes that the current MBS listings used for insertion, removal or replacement of a CRT-D in patients with NYHA class III or IV heart failure should be modified to also include patients with NYHA class II heart failure who have sinus rhythm, a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more, despite optimised medical therapy (OMT). The main comparator for the proposed medical service is the insertion, removal or replacement of an ICD.

The clinical evaluation presented in **Section B** demonstrates that CRT-D implantation significantly reduces the risk of all-cause mortality, cardiovascular mortality, and hospitalisation for heart failure, compared to ICD implantation, in the proposed patient population. Based on the fact that CRT-D has been shown to be clearly superior to ICD in direct head-to-head randomised controlled trials in terms of efficacy, the economic evaluation has been conducted as a cost-utility analysis that assesses the incremental cost-effectiveness of CRT-D compared to ICD.

D.1.1 Generation of the base case economic evaluation

The economic evaluation has been developed in three discrete steps, each of which is outlined below. Each step presents an incremental cost-effectiveness ratio (ICER) of CRT-D relative to ICD.

Step 1a

This step is a trial-based economic evaluation that estimates the incremental *cost per death avoided* for CRT-D compared with ICD over a 60-month period. This step uses the unadjusted 60 month survival data reported in NYHA II patients for each arm of the economic model. This step includes direct initial intervention costs (i.e. costs associated with CRT-D implantation, ICD implantation and optimised medical therapy), follow-up monitoring costs, costs associated with hospitalisation for heart failure, and costs associated with device-related hospitalisations. Discounting is not applied in this analysis.

Step 1b

This step is identical to Step 1a except that the proportion of patients dying over the 60-month period is determined using a Weibull function to determine the baseline hazard of death in the ICD arm (see **Section C.2**). The probability of death in this analysis is estimated in the CRT-D arm using the baseline hazard for the ICD modified by the adjusted all-cause mortality hazard ratio reported for the *a priori* identified NYHA II subgroup (HR, 0.71; 95% CI, 0.56 to 0.91; P=0.006). Discounting is not applied in this analysis.

Step 1c

This step is identical to Step 1b except that the outcome measures generated by the model in this step are converted into quality-adjusted life-years (QALYs). In this way the model generates an incremental cost per additional QALY gained for CRT-D treatment when compared to ICD treatment over a 60 month time horizon. Discounting of both costs and effects are applied in this analysis.

Step 2

This step is identical to Step 1c except that the time horizon of the economic analysis is extended to 20 years to provide a more complete description of the mean benefits CRT-D treatment offers over

ICD treatment. This analysis also captures the cost of generator replacement due to battery depletion. Discounting of both costs and effects are applied in this analysis.

Step 3 base case

This step is identical to Step 2 except that the time horizon of the economic analysis is set to a life time analysis (a maximum cohort age of 100 years) to provide a more complete description of the mean benefits CRT-D treatment offers over ICD treatment over the cohort's lifetime. Step 3 is the base-case economic evaluation. It builds on Step 2 by extrapolating health outcomes and health care resource use over the lifetime of the model cohort. This step captures the long-term costs and consequences associated with CRT-D implantation, compared to ICD implantation. Discounting of both costs and effects are applied in this analysis.

D.1.2 Type of economic evaluation

The base case economic evaluation is presented in the form of a cost-utility analysis, as appropriate in cases where there is a clear efficacy benefit associated with treatment that leads to improvements in patient morbidity and expected survival. The results of the primary analysis are expressed as the incremental cost per additional QALY gained when comparing CRT-D implantation (the proposed medical service) to ICD implantation (the main comparator).

D.2 POPULATION AND CIRCUMSTANCES OF USE

D.2.1 Population

The population of interest for the economic evaluation is patients with NYHA class II heart failure that have sinus rhythm, a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more, despite optimised medical therapy. Based on the age and gender distribution of participants enrolled in the RAFT trial (Tang et al 2010[77]) the economic model follows a cohort of patients that is 82.9% male and aged 66 years at model entry. These values are consistent with the demographic characteristics of patients who currently receive ICD implantation in Australia (Bradshaw et al 2013[18], discussed in **Section C.1**).

Table D-1 Baseline cohort characteristics

Parameter description	Parameter estimate		Source
	CRT-D	ICD	
Cohort age at model entry	66 years	66 years	RAFT baseline demographics
Male gender %	82.9%	82.9%	

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Tang et al (2010)[77]; Moss et al (2009)[58]; Bradshaw et al (2013)[18]

D.2.2 Circumstances of use

CRT-D implantation is proposed as a substitute for ICD implantation in the proposed MBS population. The specific medical services that would be performed under the proposed changes to the MBS are the same as those that are currently performed for the insertion, removal or replacement of a CRT-D in patients with NYHA class III or IV heart failure (MBS item numbers 38371, 38368, 38354, and 38350). All aspects of service delivery, including the clinical setting, medical professionals, equipment, facilities, and location will remain the same. The circumstances of use of the CRT-D technology presented in the pivotal trial matches the proposed MBS indication sought for CRT-D extremely well (see **Table D-2**). Furthermore, Australian clinical practice guidelines also support the use of CRT-D technology in this setting.

Table D-2 Comparison of patients considered for CRT-D in the pivotal trials, proposed MBS population, and Australian clinical practice guidelines

Trial populations	Proposed MBS population	Population recommended for CRT-D in Australian clinical practice guidelines
RAFT included patients with NYHA class II or III heart failure despite OMT, with: • Sinus rhythm or permanent AF or flutter with a controlled ventricular rate • LVEF ≤ 30% • QRS duration of ≥ 120 ms or paced QRS duration of ≥ 200 ms The RAFT trial included an *a priori* defined analysis by NYHA class. This provides data specific to NYHA II patients described in the proposed MBS indication. As discussed in Section C.1 these are the primary source of data for the economic analysis presented herein. MADIT-CRT included patients with NYHA I/II heart failure despite OMT, with: • Sinus rhythm • LVEF ≤ 30% • QRS duration of ≥ 120 ms	Patients with NYHA class II heart failure despite OMT, with: • Sinus rhythm • LVEF ≤ 30% • QRS duration of ≥ 150 ms	Patients with NYHA class II heart failure despite OMT, with: • LVEF ≤ 30% • QRS duration of ≥ 150 ms

Abbreviations: AF, atrial fibrillation; LVEF, left ventricular ejection fraction; MBS, Medicare Benefits Schedule; NYHA, New York Heart Association; OMT, optimised medical therapy
Source: Tang et al (2010)[77]; Moss et al (2009)[58]; NHFA/CSANZ 2011[59]

D.3 STRUCTURE AND RATIONALE OF THE ECONOMIC EVALUATION

D.3.1 Literature review

A comprehensive literature search was conducted to identify published economic evaluations that assessed the cost-effectiveness of CRT-D versus ICD for the treatment of patients with NYHA class II heart failure. The aim of this review was to identify economic models that could inform the economic evaluation of CRT-D in the proposed MBS population. The search strategies employed to identify relevant citations are shown in **Table D-3**.

Table D-3 Literature search strategies used to identify cost-effectiveness analyses of CRT-D in patients with mild chronic heart failure

Database		Search terms	Citations retrieved	Final number of citations, excluding duplicates
EMBASE.com (includes Medline and EMBASE 1966 to present) (searched 9 April 2013)	#1	'cost effectiveness analysis'/exp OR 'cost effectiveness analysis' OR 'economic evaluation'/exp OR 'economic evaluation' OR 'health economics'/exp OR 'health economics' OR 'cost minimization analysis'/exp OR 'cost minimization analysis' OR 'cost minimisation analysis' OR 'cost utility analysis'/exp OR 'cost utility analysis' OR 'quality adjusted life year'/exp OR 'quality adjusted life year' OR 'qaly'/exp OR 'qaly' OR 'life year saved'	585,988	194
	#2	'biventricular pacing':ab,ti OR (cardiac:ab,ti OR ventricular:ab,ti AND (resynchronisation:ab,ti OR resynchronization:ab,ti OR synchronisation:ab,ti OR synchronization:ab,ti)) OR crt:ab,ti	16,824	
	#3	defibrillat*:ab,ti OR icd:ab,ti	45,329	
	#4	crtd:ab,ti OR 'crt d':ab,ti	1086	
	#5	#2 AND #3	2360	
	#6	#4 OR #5	2714	
	#7	#1 AND #6	195	
Cochrane Library • Health technology assessment database • NHS economic evaluation database (searched 9 April 2013)	#1	MeSH descriptor: [Cardiac Resynchronization Therapy] explode all trees	68	15
	#2	"biventricular pacing" OR ((cardiac or ventricular) and (resynchronisation OR resynchronization or synchronisation OR synchronization))	439	
	#3	#1 OR #2	439	
	#4	MeSH descriptor: [Defibrillators] explode all trees	813	
	#5	defibrillat*	1428	
	#6	#4 OR #5	1428	
	#7	#3 AND #6	21	
Total number of identified citations				**209**
Excluded citations: • Wrong study type: the article did not report the structure or results of an economic evaluation • Wrong indication: the article did not consider patients with mild chronic heart failure • Wrong intervention: the article did not compare CRT-D with ICD • Conference abstract				 193 1 1 11
Number of included publications				**3**

Three published economic evaluations were identified that assessed the cost-effectiveness of CRT-D versus ICD for the treatment of patients with mild (NYHA class I or II) heart failure. The characteristics and results of these studies are summarised in **Table D-4.**

Only one publication was identified that specifically evaluated the cost-effectiveness of CRT-D implantation versus ICD implantation in patients with mild chronic heart failure (Noyes et al 2013[63]). This was based on clinical and health care resource use data collected within the MADIT-CRT trial over a short time horizon of four years. This time horizon does not capture full period in which the costs and effects of CRT-D treatment will be realised. However, the evaluation described by Noyes et

al accounted for differences in heart failure event and mortality rates, and health care utilisation events including hospitalisations, emergency room visits, physician visits, outpatient surgeries, and diagnostic tests and procedures. The average four-year healthcare expenditures of patients in the CRT-D arm of the MADIT-CRT trial was higher than that of patients in the ICD arm due to differences in device and implant-related costs. It was concluded that CRT-D implantation is cost-effective, compared with ICD implantation, in patients with NYHA class I or II heart failure with a low LVEF and LBBB (Noyes et al 2013[63]). In the full MADIT-CRT population (NYHA I & II patients) over the short-term it was estimated that the ICER for CRT-D compared with ICD was around $58,300 per QALY. While this is economically attractive, this ICER would be likely to reduce further if the analysis was conducted over a time period that captured the full costs and benefits associated with CRT-D and ICD implantation.

Table D-4 Summary of published economic evaluations of CRT-D versus ICD in patients with NYHA class II heart failure

Study ID	Country	Population	Intervention and comparator	Type of analysis	Key data sources	Time horizon Discount rate
Noyes (2013)[63]	US	Patients with NYHA class I or II heart failure (MADIT-CRT)	CRT-D vs ICD	CUA Trial-based evaluation Third-party payer perspective	Clinical data and utilities based on MADIT-CRT	4 years 3%
Bertoldi (2013)[15]	Brazil	Patients with heart failure due to LVSD, in NYHA class II, III or IV, and with prolonged QRS duration on electrocardiogram	CRT-D vs ICD, CRT-P or OMT	CUA Markov model Public healthcare system perspective	Clinical data sourced from a cohort study conducted at a heart failure outpatient clinic in Brazil and systematic literature review (details not published)	20 years 5%
Linde (2011)[51]	UK	Patients with NYHA class I or II heart failure, with a CRT-D or CRT-P implant (REVERSE)	CRT-ON vs CRT-OFF for patients	CUA Monte Carlo simulation Third-party payer perspective	Clinical data based on REVERSE European cohort	Lifetime 3.5%

Source: Bertoldi et al (2013)[15]; Linde et al (2011)[51]; Noyes et al (2013)[63]
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; CRT-P, cardiac resynchronisation therapy device; CUA, cost-utility analysis; ICD, implantable cardioverter defibrillator; LVSD, left ventricular ejection fraction; NYHA, New York Heart Association; OMT, optimised medical therapy

D.3.2 Software package and electronic copy of the economic evaluation

The economic evaluations were conducted using TreeAge Pro 2009. Microsoft Excel was used for other calculations and analyses as required, and these are included in <CRT-D supportive calculations.xlsx>. A total of five TreeAge files and one Excel Workbook are included with Section D of this submission.

D.3.3 Justification of the structure of the economic model

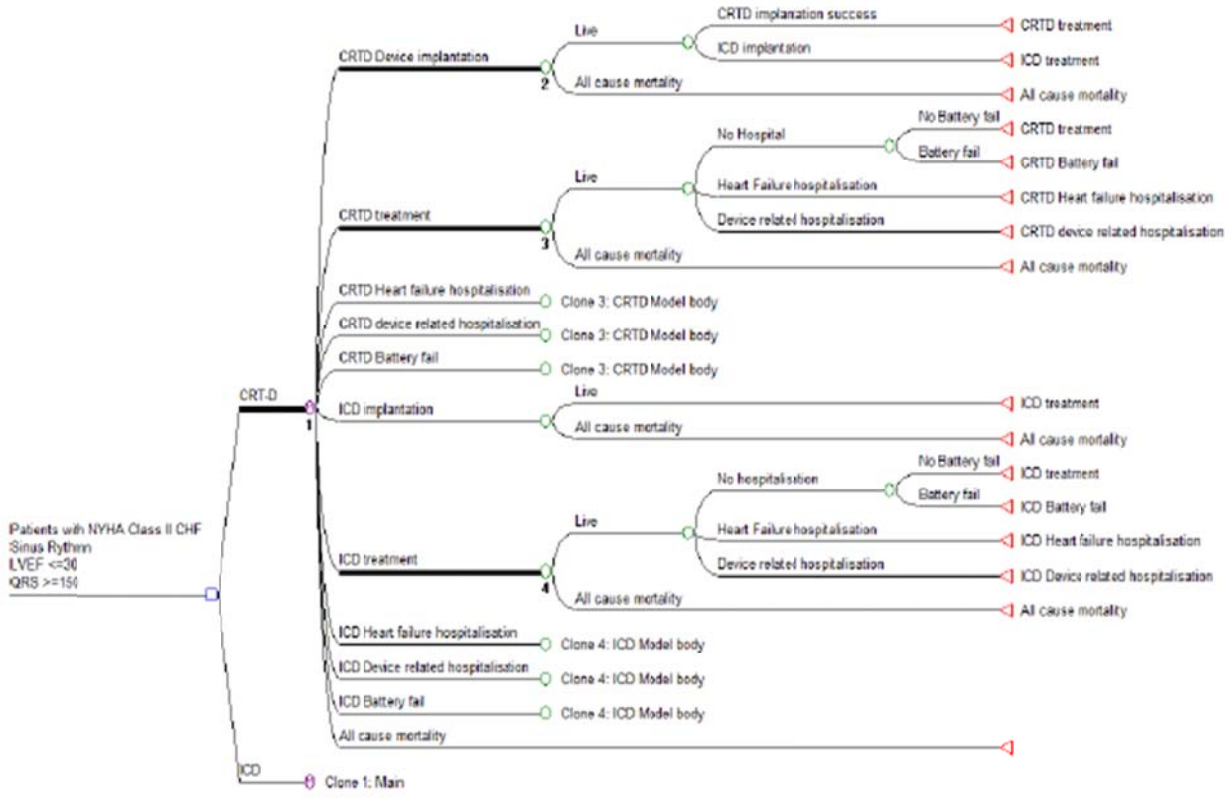
A Markov cohort model was developed to estimate the expected costs and QALYs associated with CRT-D implantation, compared to ICD implantation, in patients with NYHA class II heart failure, who have sinus rhythm, a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more,

despite optimised medical therapy. A simplified schematic of the model structure is presented in **Figure C-1**.

The economic model structure is based heavily on the survival benefits and reductions in heart failure hospitalisation reported for CRT-D in the direct head-to-head comparison of CRT-D and ICDs presented in the pivotal RCT in the patient population of interest (ie. the RAFT trial; Tang et al 2010[77]).

The health states presented in the economic model capture the pivotal drivers of cost-effectiveness, including the cost of the index procedure (ie. the initial implantation of the CRT-D or ICD device), the success rate of implantation of the CRT-D device and the cost of an ICD if a CRT-D cannot be placed. Further, the cost implications of patients being hospitalised for heart failure or device-related complications (such as lead dislodgement) and the cost of ICD or CRT-D generator replacement for battery depletion are also explicitly captured in the economic model structure.

Figure D-1 Simplified schematic of the economic model



Abbreviations CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association

The economic model has 11 health states, each of which is described for the CRT-D arm in **Table D-5**. Ten of these health states are active in the CRT-D arm of the economic model.

Table D-5 CRT-D arm economic model health states and possible transitions

Health state	Description	Possible transitions to other health states
CRT-D implantation	The entire CRT-D cohort enters this health state in the first stage of the economic model. Patients accrue the cost of the initial implantation procedure and in the vast majority of cases have a CRT-D successfully implanted. Patients in whom a CRT-D cannot be implanted receive an ICD. The cost of the placement of these devices is accrued in this health state. The costs of short term CRT-D related complications are captured here. The cohort also accrues baseline utility and the costs of OMT in this health state.	CRT-D treatment ICD treatment All-cause mortality
CRT-D treatment	The proportion of the cohort that have a successfully implanted CRT-D transition to this health state. The cohort circulates in this health state until such time as the patient needs to be hospitalized for heart failure, the implanted system suffers a longer term complication which requires that the patient is hospitalized, the battery of the device is depleted and requires a new generator to be placed, or the patient dies from all-cause mortality. While patients reside in this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	CRT-D treatment CRTD Battery fail CRTD Heart Failure hospitalisation CRTD Device related hospitalisation All-cause mortality
CRTD Heart failure hospitalization	The proportion of the cohort that are hospitalized for heart failure transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The cost of heart failure hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	CRT-D treatment CRTD Battery fail CRTD Heart Failure hospitalisation CRTD Device related hospitalisation All-cause mortality

Health state	Description	Possible transitions to other health states
CRTD device related hospitalization	The proportion of the cohort that is hospitalized for device related reasons (such as lead dislodgment or replacement) but excluding battery depletion transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The cost of a CRT-D device related hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	CRT-D treatment CRTD Battery fail CRTD Heart Failure hospitalisation CRTD Device related hospitalisation All-cause mortality
CRTD battery fail	The proportion of the cohort in which the battery of the CRTD device implanted is depleted and requires replacement transitions to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The cost of placing a new CRT-D generator device is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	CRT-D treatment CRTD Battery fail CRTD Heart Failure hospitalisation CRTD Device related hospitalisation All-cause mortality
ICD implantation	Inactive	NA

Health state	Description	Possible transitions to other health states
ICD treatment	The proportion of the cohort that have a successfully implanted ICD transition here. The cohort circulates in this health state until such time as the patient needs to be hospitalized for heart failure, the implanted system suffers a longer term complication which requires that the patient is hospitalized, the battery of the device is depleted and requires a new generator to be placed, or the patient dies from all-cause mortality. While patients reside in this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). It is appropriate to use the CRT-D utility weights in this health state as any cross-over of CRT-D to ICD therapy and its impact on utility is already captured in the utility weights derived in the CRT-D arm of the MADIT-CRT RCT. The probability of heart failure and all-cause mortality applied in this health state is that derived in the CRT-D arm of the RCT as any cross-over of CRT-D to ICD therapy and its impact on these probabilities is already captured in the RAFT trial aggregate estimates. The probability of battery depletion is specific to the ICD device in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality

Health state	Description	Possible transitions to other health states
ICD Heart failure hospitalization	The proportion of the cohort that are hospitalized for heart failure transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. Further, it is appropriate to use the CRT-D utility weights in this health state as any cross-over of CRT-D to ICD therapy and its impact on utility is already captured in the utility weights derived in the MADIT-CRT RCT. The probability of heart failure and all-cause mortality applied in this health state is that derived in the CRT-D arm of the RCT as any cross-over of CRT-D to ICD therapy and its impact on these probabilities is already captured in the RAFT trial aggregate estimates. The probability of battery depletion is specific to the ICD device in this health state. The cost of heart failure hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality

Health state	Description	Possible transitions to other health states
ICD device related hospitalization	The proportion of the cohort that is hospitalized for device related reasons (such as lead dislodgment or replacement) but excluding battery depletion transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. Further, it is appropriate to use the CRT-D utility weights in this health state as any cross-over of CRT-D to ICD therapy and its impact on utility is already captured in the utility weights derived in the MADIT-CRT RCT. The cost of ICD device related hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality
ICD battery fail	The proportion of the cohort in which the battery of the ICD device implanted is depleted and requires replacement transitions to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with CRT-D (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. Further, it is appropriate to use the CRT-D utility weights in this health state as any cross-over of CRT-D to ICD therapy and its impact on utility is already captured in the utility weights derived in the MADIT-CRT RCT. The cost of placing a new generator device related is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality

Health state	Description	Possible transitions to other health states
All-cause mortality	The proportion of the cohort that die from all-cause mortality transition to this health state. No costs or benefits are accrued in this health state.	None (this is an absorbing health state)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; NA, not applicable; OMT, optimised medical therapy; QALY, Quality adjusted life year; RCT, Randomized controlled trial

The ICD arm of the economic model is a *clone* of the CRT-D arm with 11 health states, however, in this arm of the economic model only six health states are activated. **Table D-6** describes the characteristics of each of these health states in detail.

Table D-6 ICD arm economic model health states and possible transitions

Health state	Description	Possible transitions to other health states
CRT-D implantation	Inactive	NA
CRT-D treatment	Inactive	NA
CRTD Heart failure hospitalization	Inactive	NA
CRTD device related hospitalization	Inactive	NA
CRTD battery fail	Inactive	NA
ICD implantation	The entire ICD cohort enters this health state in the first stage of the economic model. Patients accrue the cost of the initial implantation procedure. All patients have an ICD successfully implanted. The costs of short term complications related to ICD placement are captured here. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state. It is assumed that all patients will have an ICD successfully implanted.	ICD treatment All-cause mortality

Health state	Description	Possible transitions to other health states
ICD treatment	The proportion of the cohort that have a successfully implanted ICD transition here. The cohort circulates in this health state until such time as the patient needs to be hospitalized for heart failure, the implanted system suffers a longer term complication which requires that the patient is hospitalized, the battery of the device is depleted and requires a new generator to be placed, or the patient dies from all-cause mortality. While patients reside in this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with ICD (See Section C.3). The probability of heart failure and all-cause mortality applied in this health state is that derived in the ICD arm of the RCT. The probability of battery depletion is specific to the ICD device in this health state. All patients accrue the cost of background OMT while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality
ICD Heart failure hospitalization	The proportion of the cohort that are hospitalized for heart failure transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with ICD (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The probability of heart failure and all-cause mortality applied in this health state is that derived in the ICD arm of the RCT. The probability of Battery depletion is specific to the ICD device in this health state. The cost of heart failure hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality

Health state	Description	Possible transitions to other health states
ICD device related hospitalization	The proportion of the cohort that is hospitalized for device related reasons (such as lead dislodgment or replacement) but excluding battery depletion transition to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with ICD (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The cost of ICD device related hospitalisation is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality
ICD battery fail	The proportion of the cohort in which the battery of the ICD device implanted is depleted and requires replacement transitions to this health state. While patients transition through this health state in the first six months of the modeling period they accrue baseline QALY benefits (See Section C.3). After this period the cohort accrues QALY benefits seen in the follow period of the MADIT-CRT trial in patients treated with ICD (See Section C.3). As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary. The cost of placing a new ICD generator device is accrued in this health state. All patients accrue the cost of background OMT and device monitoring costs while residing in this health state.	ICD treatment ICD Battery fail ICD Heart Failure hospitalisation ICD Device related hospitalisation All-cause mortality
All-cause mortality	The proportion of the cohort that die from all-cause mortality transition to this health state. No costs or benefits are accrued in this health state.	None (this is an absorbing health state)

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; NA, not applicable; OMT, optimised medical therapy; QALY, Quality adjusted life year; RCT, Randomized controlled trial

D.3.4 Time horizon and outcomes used in the evaluation

Step 1a

In this step of the economic analysis the outcome measure used is the proportion of the cohort that dies during the 60-months follow up. This step uses the unadjusted 60 month survival data reported in NYHA II patients for each arm of the economic model. This analysis generates an incremental *cost per additional death avoided* for CRT-D compared with ICD.

Step 1b

This step is identical to Step 1a except that the proportion of patients dying over the 60-month period is determined using a Weibull function to determine the baseline hazard of death in the ICD arm (see **Section C.2**). The probability of death in this analysis is estimated in the CRT-D arm using the baseline hazard for the ICD modified by the adjusted all-cause mortality hazard ratio reported for the *a priori* identified NYHA II subgroup (HR, 0.71; 95% CI, 0.56 to 0.91; P=0.006). This analysis generates an incremental *cost per death avoided* for CRT-D compared with ICD.

Step 1c

This step is identical to Step 1b except that the outcome measures of the model in this step are converted into quality-adjusted life-years (QALYs). In this way the model generates an *incremental cost per additional QALY* gained for CRT-D treatment when compared to ICD treatment over 60 months.

Step 2

This step is identical to Step 2 except that the time horizon of the economic analysis is set to 20 years to provide a more complete description of the mean benefits CRT-D treatment offers over ICD treatment. This analysis also captures the cost of generator replacement due to battery depletion.

Step 3

This step is identical to Step 2 except that the time horizon of the economic analysis is set to a life time analysis (a maximum cohort age of 100 years) to provide a more complete description of the mean benefits CRT-D treatment offers over ICD treatment over the cohort's lifetime. Step 3 is the base-case economic evaluation. It builds on Step 2 by extrapolating health outcomes and health care resource use over the lifetime of the model cohort. This step appropriately captures the long-term costs and consequences associated with a chronic lifetime treatment such as CRT-D and ICD placement for NYHA II patients.

D.3.5 Methods used to generate results

The economic model used to generate the results is an expected value Markov cohort analysis. The economic model is based heavily on the survival benefits and reductions in heart failure hospitalisation reported in the direct head-to-head comparison of CRT-D and ICDs presented in the pivotal RCT in the patient population of interest (ie. the RAFT trial).

The economic model employs a cycle length of one month and in the base case analysis has a life-time, time horizon (the model ceases when the cohort reaches age of 100). While the model cycle length is relatively short it provides the flexibility required in the model to capture the initial implantation procedure and any short term complications associated with these index procedures.

As the utility weights applied in the economic model are determined directly from a head-to-head RCT comparison of the two interventions of interest these values are simply applied to each entire arm of the economic model over time, thereby making the apportionment of utility weights by health state unnecessary.

All-cause mortality estimates are derived directly from the Kaplan Meier curves presented in the pivotal RCT. To extrapolate these values beyond the trial period a Weibull model is used (see **Section C.2**). The use of the Weibull model allows the hazard of mortality to change over time, allowing time-dependent probabilities to be employed in the economic model, which serves to relax the Markovian assumption. A secondary analysis was also conducted assuming that hazards were constant over time (ie. using an exponential survival function). The results of this analysis are presented in the sensitivity analyses presented in **Section D.6**.

Both costs and effects are discounted at 5% per annum, in line with the PBAC and MSAC guidelines for economic analyses. The impact of discounting is explored in sensitivity analysis. Half-cycle correction is employed in the economic evaluation, as appropriate.

The economic analysis takes a health care system perspective. The analysis assumes that the initial implantation of the device, any device related hospitalisations or generator replacements due to battery depletion are performed in the private hospital sector. The analysis captures OMT therapy costs which will largely be borne by the PBS. It is assumed that patients that require hospitalisation due to heart failure are admitted to public or private hospitals.

D.4 VARIABLES IN THE ECONOMIC EVALUATION

D.4.1 Summary of input parameters

Table D-7 summarises the clinical and economic input parameters included in the economic evaluation. These are based on the pre-modelling studies described in **Section C**, and on other data sourced from the RAFT trial (Tang et al 2010[77]). Key assumptions relating to the determination of health care resource use and cost estimates for each health state within the model are discussed below. The calculations underlying each parameter estimate are presented electronically in the file <CRT-D supportive calculations.xlsx>.

Table D-7 Summary list of input parameters included in the economic evaluation

Parameter description	Parameter estimate		Source/ Notes
	CRT-D	ICD	
Clinical input parameters			
Probability of implantation success	94.7%	100%	Probability of CRT-D implant success estimated based on implant success rates reported for the RAFT trial. Probability of ICD implant success is assumed to be 100%.
Probability of implantion failure	5.3%	NA	
Probability of implant-related complications	13.3%	6.8%	RAFT trial (see Section B.6.2.1)
Probability of no implant-related complications	86.7%	93.2%	RAFT trial (see Section B.6.2.1)
Probability of device-related hospitalisation	20.0% (FU 40 months)	12.2% (FU 40 months)	RAFT trial (see Section B.6.2.1)
Baseline probability of hospitalisation for heart failure	–	33.3% (FU 60 months)	RAFT trial (see Section B.6.2.1)
Adjusted HR of hospitalisation for heart failure	0.70	1.0	RAFT trial (see Section B.6.2.1)
Unadjusted probability of all-cause mortality	31.0% (FU 60 months)	23.7% (FU 60 months)	RAFT trial (see Section B.6.2.1). Applied in Step 1a of the economic analysis only.
Baseline risk of all-cause mortality	–	Weibull function (Gamma = 1.36; Lambda=120.07)	See Section C.2
Adjusted HR of all-cause mortality	0.71	1.0	RAFT trial (see Section B.6.2.1)
Median time to generator replacement for battery depletion	5.79 years	7.12 years	NICE 2013[61]
Mean utility at baseline and for first 6 months of model	0.847	0.847	MADIT-CRT (see Table D-19)
Mean utility during follow-up and > 6 months follow-up	0.883	0.876	MADIT-CRT (see Table D-19)
Economic input parameters			
Cost of successful implantation	$75,060.32	$63,424.33	Table D-12, Table D-14
Cost of unsuccessful implantation	$70,727.44	NA	Table D-12
Cost of a device-related hospitalisation	$10,724.65	$10,687.70	Table D-15
Cost of a hospitalisation for heart failure	$6,703.30	$6,703.30	Table D-16
Cost of generator replacement for battery depletion	$53,063.53	$48,730.65	Table D-18
Annual cost of ongoing monitoring	$284.25	$284.25	MBS 11727, assumed that patients attend a device follow-up visit 3x per year
Annual cost of OMT	$529.61	$529.61	Section C.4

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; FU, Follow up; HR, Hazard Rate; ICD, implantable cardioverter defibrillator; NA, not applicable; NICE, National Institute for Health and Care Excellence; OMT, optimised medical therapy
Source: Tang et al (2010)[77]; NICE (2013)[61]

Methods used to determine clinical inputs

As discussed in **Section C.1**, the clinical characteristics of patients with NYHA class II heart failure included in the RAFT trial closely match the characteristics of the proposed MBS population. Estimates of the probability of implant success or failure, implant-related complications, device-related hospitalisations, hospitalisation for heart failure and all-cause mortality are based on the findings of this trial (Tang et al 2010[77]).

The methods used to extrapolate all-cause mortality rates are presented in **Section C.2** of this application. Utility weight estimates are discussed in **Section C.3.** The probability of device related and heart failure hospitalisation are assumed to be constant in both arms of the economic analysis. These probabilities are adjusted appropriately to the cycle length of the economic model. Details of these calculations are presented in the TreeAge economic model files accompanying this submission.

Methods used to determine economic inputs

The health care resource use and cost estimates applied to each health state within the economic evaluation are based on Australian data sourced from the May 2013 Medicare Benefits Schedule[9], the May 2013 Pharmaceutical Benefits Schedule[10] and the National Hospital Cost Data Collection Cost Weights for Australian Refined Diagnosis Related Groups (AR-DRGs) (Round 13, 2008-2009). The methods used to derive health care resource use and cost estimates have been guided by the DAP for this application and the methods used to determine resource use and cost estimates in MSAC Assessment Report 32. Cost calculations are presented electronically in the file <CRT-D supportive calculations.xlsx>.

System component unit costs are estimated based on the average benefit associated with generators and leads included on the February 2013 Prostheses List[11] (**Table D-8**).

Table D-8 CRT-D and ICD system component unit costs

Parameter description	Parameter estimate		Source
	CRT-D	ICD	
System component unit costs[a]:			
• Generator	$51,141.76	$46,808.89[b]	PL group 8.2 and 8.3
• LV lead	$6,240.00	NA	PL group 8.8.11
• Defibrillation lead	$9,000.00	$9,000.00	PL groups 8.7.5 and 8.7.6
• Pacemaker lead	$1,262.80	$1,262.80	PL groups 8.8.8 and 8.8.9
Total cost of new system	**$67,644.56**	**$57,071.69**	**Sum of costs listed above**

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LV, left ventricular; PL, Prostheses List

Source: Prostheses List (February 2013)[11]

a System component unit costs are estimated based on the average benefit associated with generators and leads included on the February 2013 Prostheses List. See worksheet named 'System component costs' in <CRT-D supportive calculations.xlsx>

b Dual chamber ICD devices as specified in final DAP

The Medicare Benefits rules applying to multiple procedures (MBS Note T8.2) have been applied, where appropriate, to avoid overestimating medical service costs incurred in relation to surgical procedures performed in the Private health care setting. The full wording of the MBS Multiple Operation Rule is shown in **Table D-9**.

Table D-9 MBS Multiple Operation Rule

Notes to the MBS
T8.2 (Multiple Operation Rule) The fees for two or more operations, listed in Group T8 (other than Subgroup 12 of that Group), performed on a patient on the one occasion (except as provided in paragraph T8.2.3) are calculated by the following rule: o 100% for the item with the greatest Schedule fee; plus o 50% for the item with the next greatest Schedule fee; plus o 25% for each other item. Note: (a) Fees so calculated which result in a sum which is not a multiple of 5 cents are to be taken to the next higher multiple of 5 cents. (b) Where two or more operations performed on the one occasion have Schedule fees which are equal, one of these amounts shall be treated as being greater than the other or others of those amounts. (c) The Schedule fee for benefits purposes is the aggregate of the fees calculated in accordance with the above formula. (d) For these purposes the term "operation" only refers to all items in Group T8 (other than Subgroup 12 of that Group). This rule does not apply to an operation which is one of two or more operations performed under the one anaesthetic on the same patient if the medical practitioner who performed the operation did not also perform or assist at the other operation or any of the other operations, or administer the anaesthetic. In such cases the fees specified in the Schedule apply. Where two medical practitioners operate independently and either performs more than one operation, the method of assessment outlined above would apply in respect of the services performed by each medical practitioner. If the operation comprises a combination of procedures which are commonly performed together and for which a specific combined item is provided in the Schedule, it is regarded as the one item and service in applying the multiple operation rule. There are a number of items in the Schedule where the description indicates that the item applies only when rendered in association with another procedure. The Schedule fees for such items have therefore been determined on the basis that they would always be subject to the "multiple operation rule". Where the need arises for the patient to be returned to the operating theatre on the same day as the original procedure for further surgery due to post-operative complications, which would not be considered as normal aftercare - see paragraph T8.2, such procedures would generally not be subject to the "multiple operation rule". Accounts should be endorsed to the effect that they are separate procedures so that a separate benefit may be paid.

Source: Medicare Benefits Schedule (1 May 2013)[9]

D.4.2 Input parameters by health state

D.4.2.1 Pre-implantation procedures

The investigative procedures performed prior to CRT-D implantation are the same as those performed prior to ICD implantation. These procedures will not be affected by the proposed changes to the MBS listings for CRT-D implantation. The economic evaluation does not capture costs with the initial diagnosis and identification of the eligible patient population as these costs are incurred prior to the start of the economic model, and as they would be the same in both arms.

D.4.2.2 CRT-D implantation

The economic evaluation assumes that placement of the left ventricular lead is successful in 94.7% of all patients who undergo a CRT-D implant procedure. This estimate is based on the overall rate of implant success reported for the pivotal RAFT trial (Tang et al 2010[77]). It is comparable with the rate of CRT-D implant success reported for the MADIT-CRT trial (92.5%), and is consistent with other published estimates of the probability of CRT-D implant success (Moss et al 2009[58]; Adabag et al 2011[2]; Al-Majed et al 2011[3]; Bertoldi et al 2011[15]; Van Rees et al 2011[79]). Based on consultation with clinical experts it is assumed that if the left ventricular lead cannot be placed, patients are likely to receive an ICD generator instead of a CRT-D generator. Only the small proportion of patients that are contraindicated for surgery and are unable to have an ICD or a CRT-D implanted are likely to be maintained on medical therapy alone, due to their increased risk of SCD.

The relative proportion of patients in the proposed MBS population that will receive transvenous (MBS 38368) or epicardial (MBS 38654) placement of the left ventricular lead as a result of the proposed changes to the MBS is expected to be similar to the relative proportion of patients currently receiving these medical services in Australia. Based on the number of Medicare services processed between July 2011 and June 2012, it is estimated that 93.7% of patients receive transvenous placement of the left ventricular lead while 6.3% of patients receive epicardial placement of the left ventricular lead (**Table D-10**). This estimate does not affect the results of the economic evaluation as both lead insertion procedures are associated with the same MBS schedule fee.

Table D-10 Estimated proportion of patients receiving transvenous or epicardial placement of the left ventricular lead

MBS item number	Item descriptor	Number of services processed between July 2011 and June 2012	Proportion (%)	MBS fee ($)
MBS 38368	Insertion of the LV lead (transvenous)	1,007	93.7%	$1224.60
MBS 38654	Insertion of the LV lead (epicardial)	68	6.3%	$1224.60
Total number of services processed for placement of LV lead		**1,075**	**100%**	**$1224.60**

Abbreviations: LV, left ventricular; MBS, Medicare Benefits Schedule
Source: Medicare Item Reports for June 2011 to June 2012. https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml

General anaesthesia is not medically necessary for the majority of patients undergoing CRT-D implantation as current clinical practice does not require the patient to be placed into asystole. The choice between general and local anaesthesia (with or without conscious sedation) is made with local institutional practice, patient preference, and possibly whether ventricular fibrillation induction is to be performed (Daubert 2012).

Based on consultation with clinical experts, it is estimated that approximately 20% of patients that undergo CRT-D implantation would receive general anaesthesia, and would therefore require additional medical services provided by an anaesthetist. The average cost of medical services provided by an anaesthetist delivering general anaesthesia during CRT-D implantation is estimated to be $226 per patient, per procedure, as reported in the DAP for MSAC Application 1223.

It is assumed that the remaining 80% of patients would receive local anaesthesia during CRT-D implantation. The cost of delivery of local anaesthesia is included in the cost of medical services performed for insertion of CRT-D system components, as per MBS Note T8.3 (Procedure Performed with Local Infiltration or Digital Block).

Hospital costs associated with CRT-D implantation are captured under AR-DRG codes F01A (for implant procedures with complications) and F01B (for implant procedures with no complications. The probability of CRT-D implant-related complications has been estimated based on the proportion of patients that experienced system-related complications within 30 days of implantation in the CRT-D arm of the RAFT trial (Tang et al 2010[77]). It is assumed that patients have the same risk of implant-related complications, regardless of whether CRT-D implantation is successful or unsuccessful (**Table D-11**).

Table D-11 Cost of hospitalisation for CRT-D implantation

Row	Parameter description	Parameter estimate	Source
Cost per hospitalisation for implantation, with complications			
A	Total average cost per hospitalisation for implantation	$69,902.00	AR-DRG F01A
B	Prostheses component cost	$57,512.00	AR-DRG F01A
C	Total cost per hospitalisation for implantation, with complications (excluding Prostheses component)	$12,390.00	Row C = A - B
Cost per hospitalisation for implantation, with no complications			
D	Total average cost per hospitalisation for implantation	$56,626.00	AR-DRG F01B
E	Prostheses component cost	$52,311.00	AR-DRG F01B
F	Total cost per hospitalisation for implantation, with no complications (excluding Prostheses component)	$4,315.00	Row F = D - E
Weighted average cost per hospitalisation for implantation			
G	Probability of implant-related complications	13.3%	RAFT trial (Table D-7)
H	Probability of no implant-related complications	86.7%	RAFT trial (Table D-7)
I	**Weighted average cost per hospitalisation for CRT-D implantation**	**$5,388.03**	**Row I = (C * G) + (F * H)**

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Groups, CRT-D, cardiac resynchronisation therapy device capable of defibrillation

Source: Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'CRT-D implant costs' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

All patients undergoing CRT-D implantation receive the medical services associated with insertion of the left ventricular lead (MBS 38368 or MBS 38654); insertion of the defibrillation lead (MBS 38384); and insertion of the pacemaker lead (MBS 38350). If the left ventricular lead can be successfully placed, patients receive medical services associated with insertion of the CRT-D generator (MBS 38371). If the left ventricular lead cannot be placed, patients receive medical services associated with insertion of an ICD generator (MBS 38387). The total cost per successful CRT-D implant procedure is estimated to be $75,060.32, and the total cost per unsuccessful CRT-D implant procedure, where an ICD is implanted instead, is estimated to be $70,727.44 (**Table D-12**).

Table D-12 Total cost per CRT-D implantation procedure

Resource type	Unit price	Quantity (no)	% of fee claimable[a]	Cost per procedure	Bearer of cost	Source
Successful CRT-D implant procedure						
Medical services						
Insertion of LV lead (transvenous)[b]	$1,224.60	0.937	100%	$1,147.14	MBS/PHI	MBS 38368
Insertion of LV lead (epicardial)[b]	$1,224.60	0.063	100%	$77.46	MBS/PHI	MBS 38654
Insertion of defibrillator lead	$1,052.65	1	50%	$526.33	MBS/PHI	MBS 38384
Insertion of pacemaker lead	$638.65	1	25%	$159.66	MBS/PHI	MBS 38350
Insertion of CRT-D generator	$287.75	1	25%	$71.94	MBS/PHI	MBS 38371
Average cost of general anaesthesia (as reported in DAP)[b]	$226.00	0.2	100%	$45.20	MBS/PHI	DAP
Hospital services						
Hospitalisation for CRT-D implantation	$5,388.03	1	NA	$5,388.03	Private hospitals	Table D-11

Resource type	Unit price	Quantity (no)	% of fee claimable[a]	Cost per procedure	Bearer of cost	Source
System components						
LV lead	$6,240.00	1	NA	$6,240.00	PHI	Table D-8
Defibrillation lead	$9,000.00	1	NA	$9,000.00		
Pacemaker lead	$1,262.80	1	NA	$1,262.80		
CRT-D generator	$51,141.76	1	NA	$51,141.76		
Total cost per successful CRT-D implantation procedure				**$75,060.32**		
Unsuccessful CRT-D implant procedure						
Medical services						
Insertion of LV lead (transvenous)[b]	$1,224.60	0.937	100%	$1,147.14	MBS/PHI	MBS 38368
Insertion of LV lead (epicardial)[b]	$1,224.60	0.063	100%	$77.46	MBS/PHI	MBS 38654
Insertion of defibrillator lead	$1,052.65	1	50%	$526.33	MBS/PHI	MBS 38384
Insertion of pacemaker lead	$638.65	1	25%	$159.66	MBS/PHI	MBS 38350
Insertion of ICD generator	$287.75	1	25%	$71.94	MBS/PHI	MBS 38387
Average cost of general anaesthesia (as reported in DAP)[b]	$226.00	0.2	100%	$45.20	MBS/PHI	DAP
Hospital services						
Hospitalisation for CRT-D implantation	$5,388.03	1	NA	$5,388.03	Private hospitals	Table D-11
System components						
LV lead	$6,240.00	1	NA	$6,240.00	PHI	Table D-8
Defibrillation lead	$9,000.00	1	NA	$9,000.00		
Pacemaker lead	$1,262.80	1	NA	$1,262.80		
ICD generator	$46,808.89	1	NA	$46,808.89		
Total cost per unsuccessful CRT-D implantation procedure				**$70,727.44**		

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; DAP, Decision Analytic Protocol; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MBS, Medicare Benefits Schedule; NA, not applicable; PHI, private health insurer
Source: Medicare Benefits Schedule (1 May 2013)[9], DAP for MSAC Application 1223, Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'CRT-D implant costs' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

a The percentage of fee claimable is determined in accordance with the MBS Multiple Operation Rule (**Table D-9**).

b Proportion of patients receiving transvenous or epicardial insertion of the left ventricular lead is estimated in **Table D-10.**

c Based on clinical opinion it is assumed that 20% of patients undergoing CRT-D implantation will receive general anaesthesia and therefore require medical services performed by an anaesthetist. The average cost of an anaesthetist delivering general anaesthetic during CRT-D implantation is sourced from the Consultation DAP for MSAC Application 1223.

D.4.2.3 ICD implantation

The economic evaluation assumes that ICD implantation is only attempted once, and that it is successful in all cases. Published estimates of the probability of ICD implant success range from 97.4% to 98.9%, therefore this assumption is likely to be conservative, and may bias the results of the economic evaluation against CRT-D (Moss et al 2009[58]; Adabag et al 2011[2]; Van Rees et al 2011[79]).

The methods used to estimate medical service, hospital and system component costs associated with ICD implantation are similar to those used to estimate the costs associated with CRT-D implantation. These calculations are shown below in **Table D-13** and **Table D-14**. The total cost per ICD implant procedure is estimated to be $63,424.33.

Table D-13 Cost of hospitalisation for ICD implantation

Row	Parameter description	Parameter estimate	Source
Cost per hospitalisation for implantation, with complications			
A	Total average cost per hospitalisation for implantation	$69,902.00	AR-DRG F01A
B	Prostheses component cost	$57,512.00	AR-DRG F01A
C	Total cost per hospitalisation for implantation, with complications (excluding Prostheses component)	$12,390.00	Row C = A - B
Cost per hospitalisation for implantation, with no complications			
D	Total average cost per hospitalisation for implantation	$56,626.00	AR-DRG F01B
E	Prostheses component cost	$52,311.00	AR-DRG F01B
F	Total cost per hospitalisation for implantation, with no complications (excluding Prostheses component)	$4,315.00	Row F = D - E
Weighted average cost per hospitalisation for implantation			
G	Probability of implant-related complications	6.8%	RAFT trial (Table D-7)
H	Probability of no implant-related complications	93.2%	RAFT trial (Table D-7)
I	**Weighted average cost per hospitalisation for ICD implantation**	**$4,863.52**	**Row I = (C * G) + (F * H)**

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Groups, ICD, implantable cardioverter-defibrillator
Source: Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'ICD implant costs' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

Table D-14 Total cost per ICD implantation procedure

Resource type	Unit price	Quantity (no)	% of fee claimable[a]	Cost per procedure	Bearer of cost	Source
Medical services						
Insertion of defibrillator lead	$1,052.65	1	100%	$1,052.65	MBS/PHI	MBS 38384
Insertion of pacemaker lead	$638.65	1	50%	$319.33	MBS/PHI	MBS 38350
Insertion of ICD generator	$287.75	1	50%	$71.94	MBS/PHI	MBS 38387
Average cost of general anaesthesia (as reported in DAP)[b]	$226.00	0.2	100%	$45.20	MBS/PHI	DAP
Hospital services						
Hospitalisation for ICD implantation	$4,863.52	1	NA	$4,863.52	Private hospitals	
System components						
ICD generator	$45,158.60	1	NA	$46,808.89	MBS/PHI	Table D-8
Defibrillation lead	$9,000.00	1	NA	$9,000.00		
Pacemaker lead	$1,262.80	1	NA	$1,262.80		
Total cost per ICD implantation procedure				**$63,424.33**		

Abbreviations: DAP, Decision Analytic Protocol; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MBS, Medicare Benefits Schedule; PHI, private health insurer
Source: Medicare Benefits Schedule (1 May 2013)[9], DAP for MSAC Application 1223, Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'ICD implant costs' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.
a The percentage of fee claimable is determined in accordance with the MBS Multiple Operation Rule (**Table D-9**).
b Based on clinical opinion it is assumed that 20% of patients undergoing ICD implantation will receive general anaesthesia and therefore require medical services performed by an anaesthetist. The average cost of an anaesthetist delivering general anaesthetic during CRT-D implantation is sourced from the Consultation DAP for MSAC Application 1223

D.4.2.4 Device-related hospitalisation

Device-related hospitalisation rates have been estimated for patients in the CRT-D and ICD arms of the model, based on data reported for the RAFT trial. This study did not specifically define 'device-related hospitalisation' as an outcome however the study protocol notes that CRT-D and ICD implant procedures are associated with a risk of device-related events including infection, erosion through the skin, and damage to the wall of the vein used in placement of the left ventricular lead (Tang et al 2009[77]). Other reasons for device-related hospitalisation may include lead dislodgements, lead malfunctions, system removal, replacement, or repositioning, lead extraction, or inappropriate shock (MSAC Assessment Report 32[54]).

In the absence of data regarding the underlying reasons for device-related hospitalisations that occurred within the RAFT trial, the average cost of a device-related hospitalisation is estimated to be approximately equal to the average cost of a hospitalisation for implantation or replacement of an ICD or CRT-D system component (AR-DRG F02Z), less the Prostheses cost component. Because Private national AR-DRG cost-weight reports do not include the full cost of medical services, the average cost of medical services administered during a hospitalisation for heart failure has been estimated based on data sourced from Public Sector AR-DRG cost-weight reports.

It is assumed that lead replacement procedures are performed during 10% of device-related hospitalisation, these costs are captured as shown in **Table D-15**. Patients that undergo lead replacement procedures incur additional CRT-D or ICD system component costs. The average cost of system components used during lead replacement procedures has been estimated based on the average benefit associated with left ventricular leads, defibrillation leads and pacemaker leads included on the February 2013 Prostheses List[11].

It is also assumed that the device-related hospitalisation rate reported for the RAFT trial does not include hospitalisation for generator replacement procedures required due to battery depletion, given that the mean duration of follow-up (40 months) is shorter than the median time to battery failure for either generator type (5.79 years for CRT-D versus 7.12 years for ICD) (Tang et al 2010[77]; NICE 2013[61]). Costs associated with generator replacement for battery depletion are discussed in **Section D.4.2.6** and captured elsewhere in the economic model.

The methods used to estimate device-related hospitalisation costs are shown in **Table D-15**. The total cost of a CRT-D related hospitalisation is estimated to be $10,724.65. The total cost of an ICD-related hospitalisation is estimated to be $10,687.70.

Table D-15 Total cost per device-related hospitalisation

Resource type	Unit price	Quantity (no)	Cost per procedure	Bearer of cost	Source
CRT-D related hospitalisation					
Medical services					
Medical service cost (Private hospital)	$1,428.56	1	$1,428.56	MBS	Based on Public AR-DRG F02Z medical service component cost weighted for length of stay in Private hospital
Hospital services					
Hospital cost (Private hospital)	$8,746.00	1	$8,746.00	Private hospitals	AR-DRG F02Z less medical and prosthesis component costs
System components					
LV lead	$6,240.00	0.03	$208.00	Private health insurance	Table D-8
Defibrillation lead	$9,000.00	0.03	$300.00		
Pacemaker lead	$1,262.80	0.03	$42.09		
Total cost per CRT-D related hospitalisation			**$10,724.65**		
ICD related hospitalisation					
Medical services					
Medical service cost (Private hospital)	$1,428.56	1	$1,428.56	MBS	Based on Public AR-DRG F02Z medical service component cost weighted for length of stay in Private hospital
Hospital services					
Hospital cost (Private hospital)	$8,746.00	1	$8,746.00	Private hospitals	AR-DRG F02Z less medical and prosthesis component costs
System components					
Defibrillation lead	$9,000.00	0.05	$450.00	Private health insurance	Table D-8
Pacemaker lead	$1,262.80	0.05	$63.14		
Total cost per ICD related hospitalisation			**$10,687.70**		

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Groups; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MBS, Medicare Benefits Schedule
Source: Medicare Benefits Schedule (1 May 2013)[9], Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), Public Sector National Cost Weights Cost Collection Report for AR-DRG v 5.2, Round 13 (2008-09), see 'Device-related hospitalisation' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

D.4.2.5 Hospitalisation for heart failure

The RAFT trial defined hospitalisation for heart failure as admission to a health care facility lasting more than 24 hours with symptoms of congestive heart failure and subsequent treatment for heart failure. The study protocol states that:

> *"Most patients admitted to hospital with heart failure would be in NYHA Class IV – symptoms at rest or with any exertion. Occasionally a heart failure patient may be admitted with worsening Class III symptoms for earlier aggressive intervention. After discharge, these*

patients may return to Class II symptoms (with more than ordinary exertion) following aggressive treatment. Similarly, in an outpatient setting, a patient with Class II symptoms may become non-compliant with medications or diet/life-style resulting in development of Class III symptoms but returns and stays in Class II when the causes and consequences are identified with the patient through education. Other transient episodes of Class III heart failure can also occur with atrial fibrillation and rapid ventricular rate, myocardial ischemia, poorly controlled hypertension etc, all of which can respond well to appropriate interventions and the return to stable Class II symptoms." (Supplementary Appendix to Tang et al 2010[77]).

Patients who are admitted to hospital for heart failure can present with a wide range of clinical signs and symptoms, including decompensated heart failure (an acute or subacute worsening of status and a consequent increase in dyspnoea, fatigue, and oedema), acute pulmonary oedema, and cardiogenic shock (NHFA/CSANZ 2011[59]). The specific medical services that would be administered during a hospitalisation for heart failure depend on the underlying reason for hospitalisation, the patient's cardiac function and clinical status, and the patient's general health. Underlying reasons for hospitalisation for heart failure include can include cardiac problems (e.g. ischaemia, arrhythmia and valvular dysfunction), non-adherence to medication or conservative management strategies, changes in drug therapy or other comorbidities. Treatment strategies can include administration of oxygen to reduce symptoms of dyspnoea, the administration of medications (e.g. IV diuretics to reduce fluid overload), assisted ventillation, inotropic therapy, or mechanical cardiac support (NHFA/CSANZ 2011[59]).

It is assumed that hospitalisation for heart failure can occur in either the Public or Private hospital setting. The average cost of a hospitalisation for heart failure is estimated to be equal to the weighted average cost of a hospitalisation for heart failure or shock with or without complications (AR-DRG F62A and AR-DRG F62B). Because Private national AR-DRG cost-weight reports do not include the full cost of medical services, the average cost of medical services administered during a hospitalisation for heart failure has been estimated based on data sourced from Public Sector AR-DRG cost-weight reports.

The methods used to estimate the average cost of a hospitalisation for heart failure with or without complications in the Public or Private setting are shown in **Table D-16.** The total average cost of hospitalisation for heart failure is estimated to be $6,703.30.

Table D-16 Total cost per hospitalisation for heart failure

Resource type	Unit price	Quantity (no)[a]	Cost per procedure	Bearer of cost	Source
Medical services					
Medical service cost for hospitalisation for heart failure with complications (Private hospital)	$2,240.11	0.051	$113.69	MBS	AR-DRG F62A[b]
Medical service cost for hospitalisation for heart failure with complications (Public hospital)	$1,606.00	0.223	$358.29	Other govt health budget	AR-DRG F62A[c]
Medical service cost for hospitalisation for heart failure with no complications (Private hospital)	$1,026.54	0.571	$159.47	Private hospitals	AR-DRG F62B[b]
Medical service cost for hospitalisation for heart failure with no complications (Public hospital)	$668.00	0.155	$381.29	Other govt budget	AR-DRG F62B[c]
Hospital services					
Hospitalisation for heart failure with complications (Private hospital)	$9,290.00	0.051	$471.51	Private hospitals	AR-DRG F62A[d]
Hospitalisation for heart failure with complications (Public hospital)	$9,587.00	0.223	$2,138.83	Other govt budget	AR-DRG F62A[d]
Hospitalisation for heart failure with no complications (Private hospital)	$4,120.00	0.571	$640.05	Private hospitals	AR-DRG F62B[d]
Hospitalisation for heart failure with no complications (Public hospital)	$4,275.00	0.155	$2,440.16	Other govt budget	AR-DRG F62B[d]
Total cost per hospitalisation for heart failure			**$6,703.30**		

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Groups; MBS, Medicare Benefits Schedule

Source: Medicare Benefits Schedule (1 May 2013)[9], Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), Public Sector National Cost Weights Cost Collection Report for AR-DRG v 5.2, Round 13 (2008-09), see 'Hospitalisation for HF' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

a Proportion of patients with or without complications in the Public and Private settings estimated from number of separations reported for AR-DRG F62A and F62B.

b Ward Medical costs based on Public AR-DRG Ward Medical costs and private AR-DRG average length of stay see <CRT-D supportive calculations.xlsx> for full details of calculations.

c Ward Medical cost component of AR-DRG

d AR-DRG cost less Ward Medical component

D.4.2.6 Generator replacement for battery depletion

The median time to generator replacement for battery depletion is estimated to be 5.79 years for CRT-D and 7.12 years for ICD, based on a recent NICE assessment of implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (NICE 2013[61]).

Replacement of a CRT-D or ICD generator is a relatively straightforward process and is performed as a same day procedure. The methods used to estimate the average cost of generator replacement in the Private setting are shown in **Table D-17** and **Table D-18**. In brief, the opportunity cost of hospitalisation for the replacement of the generator in day-stay patients is estimated from the cost of a day's hospitalisation for the replacement of an ICD component as reported in AR-DRG F02Z (excluding prosthesis costs).

Table D-17 Cost of hospitalisation for CRT-D or ICD generator replacement

Row	Parameter description	Parameter estimate	Source
A	Average length of stay	5.41 days	AR-DRG F02Z
B	Total average cost of hospitalisation for implantation or replacement of a CRT-D or ICD system component	$23,900.00	AR-DRG F02Z
C	Prostheses component cost	$15,060.00	AR-DRG F02Z
D	Total cost of hospitalisation for implantation or replacement of a CRT-D or ICD system component (excluding Prostheses component)	$8,840.00	Row D = B - C
E	**Hospital cost for day stay procedure per generator replacement**	**$1,634.01**	**Row E = D / A**

Abbreviations: AR-DRG, Australian Refined Diagnosis Related Groups; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator
Source: Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), see 'Generator replacement' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

Table D-18 Total cost per CRT-D or ICD generator replacement

Resource type	Unit price	Quantity (no)	Cost per procedure	Bearer of cost	Source
CRT-D generator replacement					
Medical services Replacement of CRT-D generator	$287.75	1	$287.75	MBS	MBS 38371
Hospital services Hospitalisation for generator replacement	$1,634.01	1	$1,634.01	Private hospitals	Table D-17
System components CRT-D generator	$51,141.76	1	$51,141.76	Private health insurance	Table D-8
Total cost per CRT-D generator replacement			**$53,063.53**		
ICD generator replacement					
Medical services Replacement of ICD generator	$287.75	1	$287.75	MBS	MBS 38387
Hospital services Hospitalisation for generator replacement	$1,634.01	1	$1,634.01	Private hospitals	Table D-17
System components ICD generator	$45,158.60	1	$46,808.89	Private health insurance	Table D-8
Total cost per ICD generator replacement			**$48,730.65**		

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Schedule
Source: Medicare Benefits Schedule (1 May 2013)[9], Private Sector National Cost Weights Cost Collection Report for AR-DRG v 5.1, Round 13 (2008-09), Public Sector National Cost Weights Cost Collection Report for AR-DRG v 5.2, Round 13 (2008-09), Prostheses List (February 2013), see 'Generator replacement' worksheet of <CRT-D supportive calculations.xlsx> for full details of calculations.

D.4.2.7 Ongoing monitoring and optimised medical therapy

MBS item number 11727 is used for ongoing monitoring of patients after CRT-D or ICD implantation. It is assumed that patients attend follow-up visits three times per year, meaning that the annual cost of monitoring is $284 per patient, in both arms of the model.

The annual cost of optimised medical therapy is estimated to be $530 per patient, per year, as shown in **Section C.4**.

D.4.2.8 Utility weights

As discussed in **Section C.3**, the economic evaluation uses utility weight estimates sourced from the pivotal MADIT-CRT trial (Noyes et al 2013[63]). These were elicited from patients with NYHA class I or II heart failure at baseline and after CRT-D or ICD implantation, over a mean follow-up duration of 28 months.

Slight adjustments have been made to account for the fact that participants in the CRT-D arm of the MADIT-CRT trial had a higher mean utility values at baseline than participants in the ICD arm. These adjustments allow all patients to enter the model with the same preference-based health-related quality of life but do not affect the magnitude of utility gain applied to each arm of the model (**Section C.3**; **Table D-19**).

These estimates are subjected to a range of sensitivity analyses presented in **Section D.6** of this submission. A supplementary analysis in which all preference-based health-related quality of life weighting of survival is removed (ie. a cost per life-year-saved analysis) is presented in Section D.5 of this submission).

Table D-19 Utility weights included in the economic evaluation

Row	**Parameter description**	**Parameter estimate**		**Source**
		CRT-D	**ICD**	
Utility weight estimates reported for the MADIT-CRT trial				
A	Number of patients	748	503	MADIT-CRT (See Section C.3)
B	Mean utility at baseline	0.848	0.845	MADIT-CRT (See Section C.3)
C	Mean utility during follow up	0.884	0.874	MADIT-CRT (See Section C.3)
D	Percentage change in mean utility from baseline	4.25%	3.43%	Row D = (C – B)/B
Calculation of adjusted utility weight estimates included in the economic evaluation				
E	Adjusted mean utility at baseline	0.847	0.847	Row E = weighted average of utilities in Row B
F	Adjusted mean utility during follow-up	0.883	0.876	Row F = D + E

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator
Source: Noyes et al (2013)[63]

D.4.2.9 Discount rate

Both costs and effects are discounted at 5% per annum, in line with the PBAC and MSAC guidelines for economic analyses. The impact of discounting is explored in sensitivity analysis.

D.5 RESULTS OF THE ECONOMIC EVALUATION

D.5.1 Health care costs by step and by resource type

Table D-20 presents the costs generated by the economic model, by step and by resource type. In the analyses with shorter time horizons (Step 1a–1c) the cost of the index implantation of CRT-D or ICD has the most bearing on the incremental costs generated by the economic model. In the Steps where the time horizon is extended (Step 2 and 3) the cost of the index procedure remains an important driver of incremental cost, however, the costs of generator replacement due to battery depletion also contributes considerably to the incremental costs generated by the model.

Table D-20 Health care costs by model step and resource type

Resource item description	CRT-D	ICD	Incremental	% Total incremental
Step 1a				
Index implantation	$74,832.02	$63,424.32	$11,407.70	92.28%
Heart failure hospitalisation	$1,613.73	$2,192.89	-$579.16	-4.69%
Generator replacement due to battery depletion	$0.00	$0.00	$0.00	0.00%
Device-related hospitalisation	$3,050.45	$1,683.22	$1,367.23	11.06%
Monitoring	$1,233.54	$1,175.65	$57.89	0.47%
OMT	$2,319.91	$2,212.07	$107.84	0.87%
Total	***$83,049.65***	***$70,688.15***	***$12,361.50***	***100.00%***
Step 1b				
Index implantation	$74,831.23	$63,424.32	$11,406.91	92.32%
Heart failure hospitalisation	$1,644.67	$2,242.04	-$597.37	-4.83%
Generator replacement due to battery depletion	$0.00	$0.00	$0.00	0.00%
Device-related hospitalisation	$3,108.92	$1,720.94	$1,387.98	11.23%
Monitoring	$1,256.81	$1,201.58	$55.23	0.45%
OMT	$2,363.27	$2,260.38	$102.89	0.83%
Total	***$83,204.91***	***$70,849.26***	***$12,355.65***	***100.00%***
Step 1c				
Index implantation	$74,831.23	$63,424.32	$11,406.91	93.22%
Heart failure hospitalisation	$1,462.79	$1,998.50	-$535.71	-4.38%
Generator replacement due to battery depletion	$0.00	$0.00	$0.00	0.00%
Device-related hospitalisation	$2,765.13	$1,534.01	$1,231.12	10.06%
Monitoring	$1,120.35	$1,073.54	$46.82	0.38%
OMT	$2,109.07	$2,021.86	$87.21	0.71%
Total	***$82,288.57***	***$70,052.23***	***$12,236.34***	***100.00%***
Step 2				
Index implantation	$74,831.23	$63,424.32	$11,406.91	37.06%
Heart failure hospitalisation	$2,872.52	$3,511.56	-$639.04	-2.08%
Generator replacement due to battery depletion	$46,758.92	$30,364.28	$16,394.63	53.26%
Device-related hospitalisation	$5,429.95	$2,695.40	$2,734.54	8.88%
Monitoring	$2,177.35	$1,868.47	$308.88	1.00%
OMT	$4,078.05	$3,502.67	$575.38	1.87%
Total	***$136,148.01***	***$105,366.71***	***$30,781.30***	***100.00%***

Resource item description	CRT-D	ICD	Incremental	% Total incremental
Step 3				
Index implantation	$74,831.23	$63,424.32	$11,406.91	35.1%
Heart failure hospitalisation	$2,990.62	$3,576.35	-$585.73	-1.8%
Generator replacement due to battery depletion	$48,681.33	$30,924.53	$17,756.80	54.6%
Device-related hospitalisation	$5,653.19	$2,745.14	$2,908.05	8.9%
Monitoring	$2,265.89	$1,902.51	$363.39	1.1%
OMT	$4,243.00	$3,566.08	$676.92	2.1%
Total	***$138,665.26***	***$106,138.92***	***$32,526.34***	***100.0%***

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; NA, not applicable; OMT, optimised medical therapy

D.5.2 Health outcomes by step and by health state

Table D-21 presents the outcomes generated by the economic model, by step and by health state. The results of Step 1a (using unadjusted crude survival estimates from each arm of the RAFT trial) and Step 1b (using a baseline hazard based on a Weibull function) and the adjusted HR for all-cause mortality show similar results. However, Step 1b should be considered the more accurate representation of survival benefits as this analysis has been adjusted (through the adjusted HR) for any slight imbalances in patient characteristics present at baseline in the RAFT RCT.

Table D-21 Health outcomes by model step and health state

Resource item description	CRT-D	ICD	Incremental
Step 1a (% Deaths)			
CRT-D implantation	NA	NA	NA
CRT-D treatment	NA	NA	NA
CRTD Heart failure hospitalization	NA	NA	NA
CRTD device related hospitalization	NA	NA	NA
CRTD battery fail	NA	NA	NA
ICD implantation	NA	NA	NA
ICD treatment	NA	NA	NA
ICD Heart failure hospitalization	NA	NA	NA
ICD device related hospitalization	NA	NA	NA
ICD battery fail	NA	NA	NA
All-cause mortality	23.7%	31.0%	7.3%
Total	***23.7%***	***31.0%***	***7.3%***
Step 1b (% Deaths)			
CRT-D implantation	NA	NA	NA
CRT-D treatment	NA	NA	NA
CRTD Heart failure hospitalization	NA	NA	NA
CRTD device related hospitalization	NA	NA	NA
CRTD battery fail	NA	NA	NA
ICD implantation	NA	NA	NA
ICD treatment	NA	NA	NA
ICD Heart failure hospitalization	NA	NA	NA
ICD device related hospitalization	NA	NA	NA
ICD battery fail	NA	NA	NA

Resource item description	CRT-D	ICD	Incremental
All-cause mortality	24.1%	32.2%	8.1%
Total	***24.1%***	***32.2%***	***8.1%***
Step 1c (QALYs)			
CRT-D implantation	0.035	0.000	0.035
CRT-D treatment	3.249	0.000	3.249
CRTD Heart failure hospitalization	0.015	0.000	0.015
CRTD device related hospitalization	0.018	0.000	0.018
CRTD battery fail	0.000	0.000	0.000
ICD implantation	0.000	0.035	-0.035
ICD treatment	0.182	3.264	-3.083
ICD Heart failure hospitalization	0.001	0.022	-0.021
ICD device related hospitalization	0.001	0.010	-0.009
ICD battery fail	0.000	0.000	0.000
All-cause mortality	0.000	0.000	0.000
Total	***3.500***	***3.332***	***0.169***
Step 2 (QALYs)			
CRT-D implantation	0.035	0.000	0.035
CRT-D treatment	6.264	0.000	6.264
CRTD Heart failure hospitalization	0.030	0.000	0.030
CRTD device related hospitalization	0.035	0.000	0.035
CRTD battery fail	0.062	0.000	0.062
ICD implantation	0.000	0.035	-0.035
ICD treatment	0.351	5.644	-5.293
ICD Heart failure hospitalization	0.002	0.038	-0.037
ICD device related hospitalization	0.002	0.018	-0.016
ICD battery fail	0.003	0.045	-0.043
All-cause mortality	0.000	0.000	0.000
Total	***6.784***	***5.781***	***1.003***
Step 3 (QALYs)			
CRT-D implantation	0.035	0.000	0.035
CRT-D treatment	6.519	0.000	6.519
CRTD Heart failure hospitalization	0.031	0.000	0.031
CRTD device related hospitalization	0.037	0.000	0.037
CRTD battery fail	0.065	0.000	0.065
ICD implantation	0.000	0.035	-0.035
ICD treatment	0.365	5.747	-5.382
ICD Heart failure hospitalization	0.002	0.039	-0.037
ICD device related hospitalization	0.002	0.019	-0.017
ICD battery fail	0.003	0.046	-0.043
All-cause mortality	0.000	0.000	0.000
Total	***7.059***	***5.886***	***1.173***

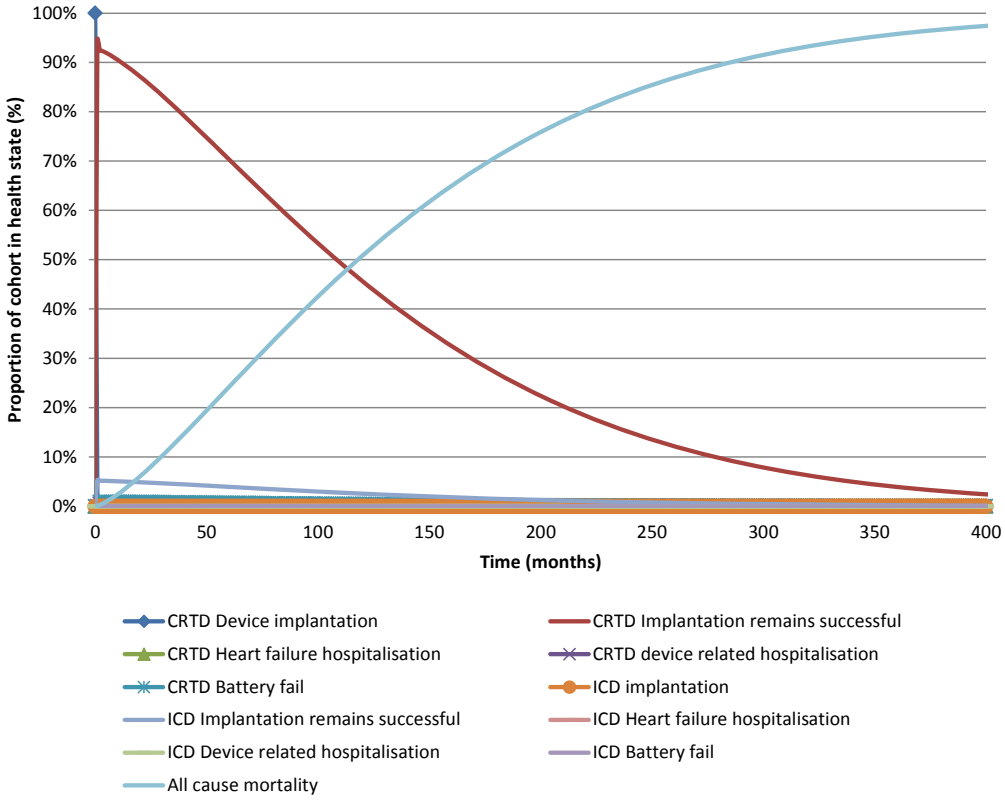
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; NA, not applicable; QALY, Quality-adjusted life-year

D.5.3 Markov traces

Figure D-2 presents the Markov trace for the CRTD arm of the economic model in the base case analysis (Step 3). The proportion of the cohort residing in each health state over the remaining life time of the modelled patient cohort is presented.

It is important to note that the model is designed as a cohort analysis which deals with a group of individuals with similar characteristics – rather than an individual patient. In a cohort analysis, the expected value is calculated by multiplying the percentage of the cohort in a health state by the incremental cost or utility assigned to that health states, and aggregating the products across health states and cycles to obtain the overall expected value. This means that the probability of being in the health state (as well as its interpretation) is associated with the aggregate study cohort – not specific and adherent to any individual patients.

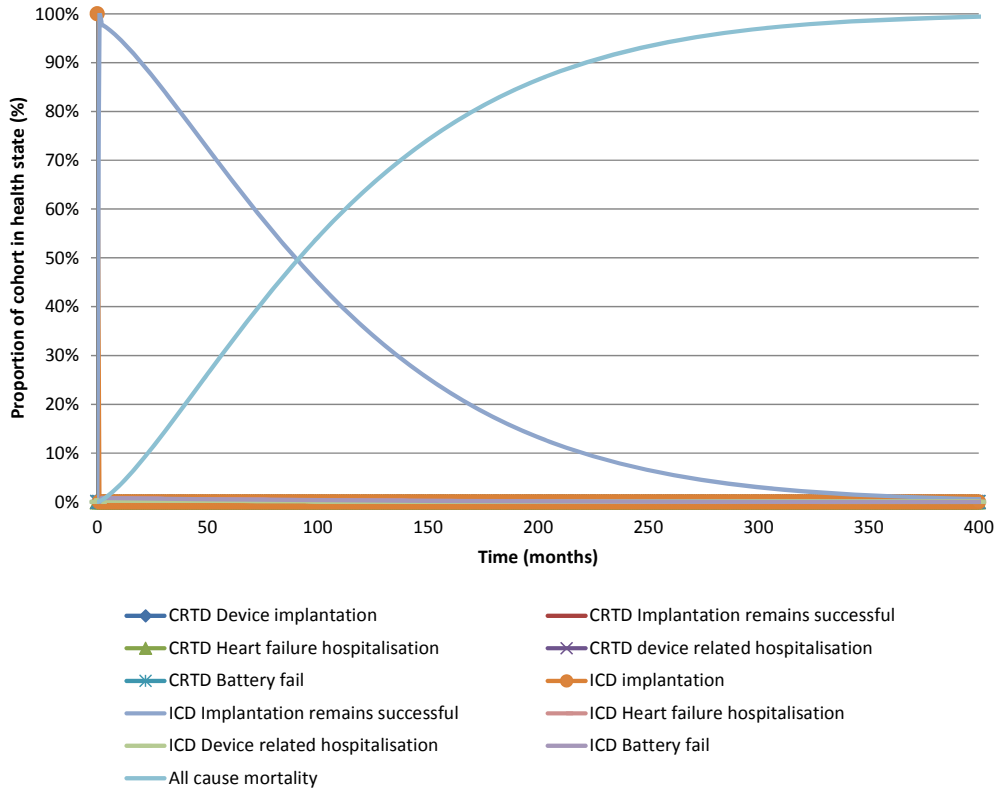
Figure D-2 Markov trace: CRT-D arm of the economic model



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator

Figure D-3 presents the Markov trace for the ICD arm of the economic model in the base case analysis (Step 3). The proportion of the cohort residing in each health state over the remaining life time of the modelled patient cohort is presented.

Figure D-3 Markov trace: ICD arm of the economic model



Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator

D.5.4 Incremental costs and effectiveness

Table D-22 presents the incremental cost-effectiveness ratio (ICER) estimates for each step of the economic analysis.

In Step 1a the model estimates that CRT-D treatment costs $169,335.60 to avoid a patient death at 60 months compared to ICD treatment. This estimate is similar to that presented in Step 1b where the model estimates that it costs $152,621.27 to avoid a patient death at 60 months compared to ICD treatment. As noted previously, Step 1b should be considered to produce more accurate representation of survival benefits than Step 1a as this analysis has been adjusted (through the adjusted HR) for any slight imbalances in patient characteristics present at baseline in the RAFT RCT.

In Step 1c the model estimates that CRT-D treatment costs around $72,422.51 per QALY gained compared to ICD over 60 months. As discussed previously, this result is based on a truncated estimate of patient survival which will markedly underestimate the survival benefits of CRT-D over ICD over a patient's lifetime.

In Step 2 the model estimates that CRT-D treatment costs around $30,704.02 per QALY gained compared to ICD over 20 years. This result is similar to the base case presented in Step 3 as the majority of the patient cohorts in each arm of the model have entered the all-cause mortality absorbing health state at this time horizon.

In the base case analysis CRT-D is shown to be cost-effective and economically attractive compared to ICD at ***$27,737.11 per QALY***.

Table D-22 Health outcomes by model step and health state

Resource item description	CRT-D	ICD	Incremental
Step 1a (Cost per death avoided at 60 months)			
Cost	$83,049.65	$70,688.15	$12,361.50
Effect (% Deaths)	23.7%	31.0%	7.3%
		Cost per death avoided	***$169,335.60***
Step 1b (Cost per death avoided at 60 months)			
Cost	$83,204.91	$70,849.26	$12,355.65
Effect (% Deaths)	24.1%	32.2%	8.1%
		Cost per death avoided	***$152,621.27***
Step 1c (Cost per QALY at 60 months)			
Cost	$82,288.57	$70,052.23	$12,236.34
Effect (QALYs)	3.500	3.332	0.169
		Cost per QALY	***$72,422.51***
Step 2 (Cost per QALY at 20 years)			
Cost	$136,148.01	$105,366.71	$30,781.30
Effect (QALYs)	6.784	5.781	1.003
		Cost per QALY	***$30,704.02***
Step 3 (Cost per QALY lifetime – base case)			
Cost	$138,665.26	$106,138.92	$32,526.34
Effect (QALYs)	7.059	5.886	1.173
		Cost per QALY	***$27,737.11***

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; QALYs, quality-adjusted life-years

Table D-23 presents a supplementary analysis in which all preference-based health-related quality of life weighting of survival is removed from the base case analysis (ie. a cost per life-year-saved analysis). This analysis generates an ICER of $25,445.66 per life-year-saved for CRT-D compared to ICD over the cohort's lifetime. This is a similar estimate to that generated by Step 3, albeit using a different outcome metric.

Table D-23 Supplementary cost-effectiveness analysis 1 (cost per life year saved)

Resource item description	CRT-D	ICD	Incremental
Supplementary economic analysis 1			
Cost	$138,665.26	$106,138.92	$32,526.34
Effect (Life-years-saved)	8.012	6.734	1.278
		Cost per life year saved	***$25,445.66***

D.6 SENSITIVITY ANALYSES

Table D-24 presents a range of sensitivity analyses applied to the base case economic analysis (Step 3). The base case economic analysis was most sensitive to changes in the estimates of all-cause mortality benefits associated with CRT-D treatment, the cost and duration of generator replacement due to battery depletion and the preference-based health-related quality of life estimates applied in

the analysis. Regardless, when reasonable extremes of these input parameters were applied to the analysis CRT-D remained economically attractive.

Table D-24 Health outcomes by model step and health state

Resource item description	Incremental cost	Incremental effect	ICER (Cost per QALY)
Base case	***$32,526.34***	***1.173***	***$27,737.11***
Costs			
CRTD total MBS index implantation cost increased by 20%	$32,931.89	1.173	$28,082.95
CRTD total MBS index implantation cost decreased by 20%	$32,120.79	1.173	$27,391.28
CRTD implantation hospital costs increased by 20%	$33,603.95	1.173	$28,656.05
CRTD implantation hospital costs decreased by 20%	$31,448.73	1.173	$26,818.18
LV lead cost increased by 20%	$33,795.11	1.173	$28,819.07
LV lead cost decreased by 20%	$31,257.57	1.173	$26,655.16
Pace lead cost increased by 20%	$32,527.65	1.173	$27,738.23
Pace lead cost decreased by 20%	$32,525.03	1.173	$27,735.99
Defibrillator lead cost increased by 20%	$32,535.69	1.173	$27,745.09
Defibrillator lead cost decreased by 20%	$32,516.99	1.173	$27,729.14
Device-related hospitalization cost increased by 20%	$33,107.95	1.173	$28,233.09
Device-related hospitalization cost decreased by 20%	$31,944.73	1.173	$27,241.14
Heart failure hospitalization cost increased by 20%	$32,409.19	1.173	$27,637.22
Heart failure hospitalization cost decreased by 20%	$32,643.49	1.173	$27,837.01
Cost of hospitalization for generator replacement due to battery depletion increased by 20%	$36,077.70	1.173	$30,765.57
Cost of hospitalization for generator replacement due to battery depletion decreased by 20%	$28,974.98	1.173	$24,708.66
Monitoring costs doubled	$32,889.72	1.173	$28,046.99
Monitoring costs halved	$32,344.65	1.173	$27,582.17
OMT costs doubled	$33,203.26	1.173	$28,314.36
OMT costs halved	$32,187.88	1.173	$27,448.49
Discount rate decreased to 3% per annum for costs and effects	$36,753.11	1.498	$24,540.12
Discount rate decreased to 0% per annum for costs and effects	$46,309.88	2.266	$20,432.70
Effects			
Preference based quality of life weighting for survival removed (ie. Cost per LYS analysis)	$32,526.34	1.278	$25,445.66 (cost per LYS)
Baseline all-cause mortality estimate based on constant hazards (exponential survival function Lambda = 0.00608) rather than a Weibull survival function	$36,787.50	1.407	$26,140.10
Hazard ratio for all-cause mortality Increased by 1 SEM (to 0.834)	$27,574.91	0.632	$43,654.95
Hazard ratio for all-cause mortality decreased by 1 SEM (to 0.586)	$38,574.17	1.833	$21,038.90
Hazard ratio for heart failure hospitalisation increased to 0.85	$33,115.81	1.173	$28,239.79
Hazard ratio for heart failure hospitalisation decreased 0.75	$32,329.72	1.173	$27,569.44
Probability of device-related hospitalization for CRT-D increased by 20%	$33,602.18	1.173	$28,654.55

Resource item description	Incremental cost	Incremental effect	ICER (Cost per QALY)
Base case	***$32,526.34***	***1.173***	***$27,737.11***
Probability of device-related hospitalization for CRT-D decreased by 20%	$31,450.50	1.173	$26,819.68
Probability of lead replacement required at device related hospitalization doubled	$32,683.53	1.173	$27,871.16
Probability of lead replacement required at device related hospitalization halved	$32,447.75	1.173	$27,670.10
CRT-D battery depletion time increased by 20%	$24,770.57	1.173	$21,123.31
CRT-D battery depletion time decreased by 20%	$44,135.85	1.173	$37,637.22
Utility weight set to parity in both model arms	$32,526.34	1.129	$28,818.04
Utility weight improvement starting at 1 month rather than 6 months	$32,526.34	1.176	$27,668.90
Utility weight improvement starting at 12 months rather than 6 months	$32,526.34	1.169	$27,818.36
Utility weight assumed to decline 5% per annum after 48 months (ie. follow up duration in MADIT-CRT trial)	$32,526.34	0.819	$39,724.32
Utility weight set to parity in both arms and reduced to 0.70	$32,526.34	0.767	$42,409.44
Utility weight set to parity in both arms and reduced to 0.90	$32,526.34	1.150	$28,272.96
Treatment effect (hazard ratio) of all-cause mortality in the CRT-D arm set to 1.0 (ie. no treatment effect) after 12 years (twice longest duration of follow-up)	$30,393.46	0.940	$32,346.49
Treatment effect (hazard ratio) of heart failure hospitalisation in the CRT-D arm set to 1.0 (ie. no treatment effect) after 12 years (twice longest duration of follow-up)	$32,726.19	1.173	$27,907.53
Multivariate sensitivity analyses			
Cost of hospitalization for generator replacement due to battery depletion increased by 20% + Hazard ratio for all-cause mortality Increased by 1 SEM (to 0.834) + Utility weight set to parity in both arms and reduced to 0.70	$27,840.34	0.466	$59,757.25
Cost of hospitalization for generator replacement due to battery depletion decreased by 20% + Hazard ratio for all-cause mortality decreased by 1 SEM (to 0.586) + Utility weight set to parity in both arms and increased to 0.90	$38,259.08	1.823979	$20,975.62

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter defibrillator; ICER, Incremental cost-effectiveness ratio; LYS, life year saved; LV, left ventricular; MBS, Medicare Benefits Scheme; QALY, Quality adjusted life year; OMT, optimised medical therapy; SEM, standard error of the mean

E ESTIMATED EXTENT OF USE AND FINANCIAL IMPLICATIONS

The net financial impact was calculated for patients that would receive reimbursement for CRT-D through the MBS (i.e. private patients). The net financial impact to the MBS is $73,972 in 2014 which is expected to increase to $97,582 in 2018 (**Table E-8**). The net financial impact to healthcare (including MBS and private insurance costs (private hospitals and prostheses list)) is $2,064,177 in 2014 which is expected to increase to $2,722,999 in 2018.

E.1 JUSTIFICATION OF THE SELECTION OF SOURCES OF DATA

As discussed in the DAP and Section A, CRT-D is a direct substitute for ICD. Therefore, the financial impact analysis presented in this submission takes a market-share approach.

The analysis presents two scenarios:

- CRT-D is reimbursed for patients with NYHA II heart failure with LVEF ≤ 30% and a QRS ≥ 150 ms (i.e., world with CRT-D)
- CRT-D is not reimbursed in this population (i.e., world without CRT-D)

As discussed in Section A, MBS benefits are available to NYHA class II patients for the insertion of an ICD device (MBS item 38387). It is expected that a proportion of NYHA class II patients currently receiving ICD, would receive CRT-D if it were reimbursed. Therefore, MBS item 38387 for ICD generator was used to estimate the incidence of patients receiving CRT-D. However, MBS item 38387 includes patients with NYHA class II and class III disease with LVEF of less than or equal to 35%. To estimate the percentage of patients that would receive CRT-D, seven KOLs were asked to estimate the proportion of patients that are currently eligible to receive MBS item 38387 that would meet the criteria to receive CRT-D (NYHA class II patients with a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more). Estimates ranged from 10% to less than 40% of patients, with 20% the most common response. Therefore, in the base case analysis, it was estimated that 20% of patients receiving MBS item 38387 would receive CRT-D. A sensitivity analysis is presented with the upper and lower ranges of estimates.

As discussed in Section D, it is estimated that 93.7% of patients receive transvenous placement of the left ventricular lead while 6.3% of patients receive epicardial placement of the left ventricular lead.

As discussed in Section D, it is estimated that that placement of the left ventricular lead is successful in 94.7% of all patients who undergo a CRT-D implant procedure. Based on consultation with clinical experts it is assumed that if the left ventricular lead cannot be placed, patients are likely to receive an ICD generator instead of a CRT-D generator. Patients where the left ventricular lead cannot be placed incur the same MBS and hospital costs as a patient receiving a successful CRT-D.

E.2 ESTIMATED USE OF CRT-D

E.2.1 Number of patients receiving CRT-D

As described above, the incidence of patients receiving CRT-D is based on the number of patients receiving an ICD (MBS item 38387). **Table E-1** shows the number of patients receiving MBS item 38387 between 2007 and 2012.

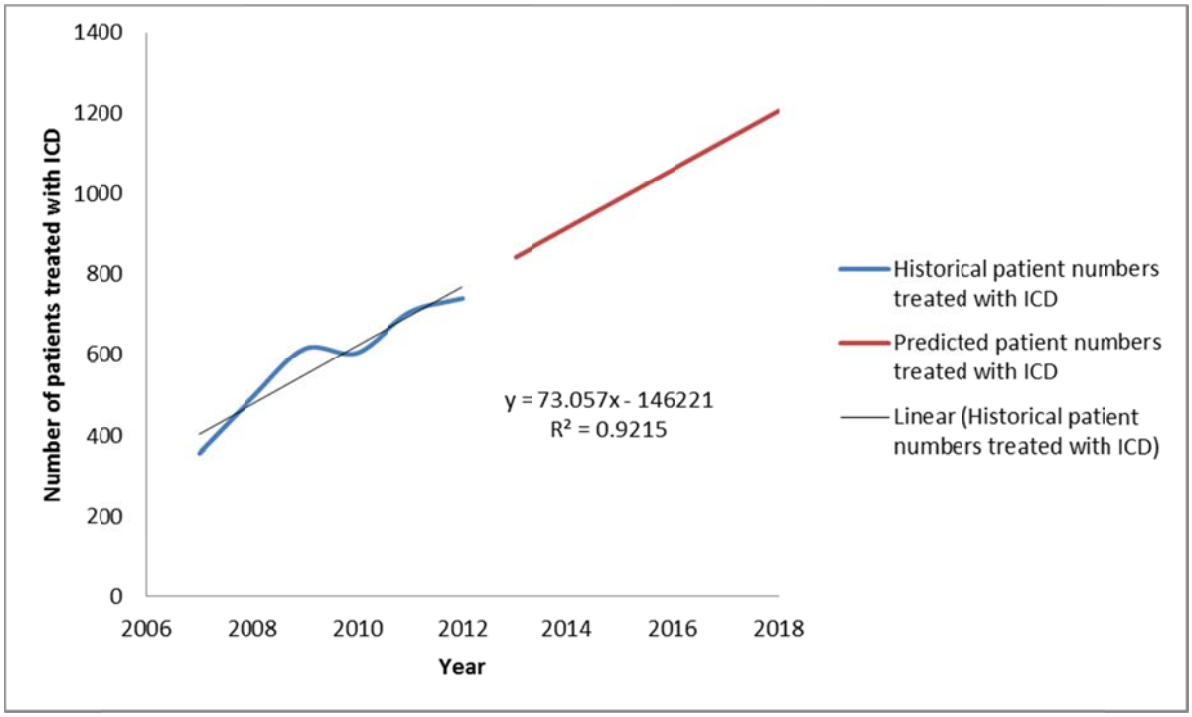
Table E-1 Number of patients receiving ICD in Australia

MBS item number	Year					
	2007	2008	2009	2010	2011	2012
38387	357	493	616	606	707	742

Abbreviations: ICD, implantable cardioverter defibrillator; MBS, Medicare Benefits Schedule

To estimate the size of the current population receiving CRT-D if it were listed on the MBS, it was assumed that the CRT-D population would increase linearly. Therefore, the estimated number of patients receiving ICD treatment for the years 2007 and 2012 were graphed and then extrapolated to 2018 using linear regression (**Figure E-1**).

Figure E-1 Estimated NYHA class II and class III patient population treated with ICD



Abbreviations: ICD, implantable cardioverter defibrillator

Table E-2 summarises the estimated number of patients receiving CRT-D. Based on clinical advice from KOLs, it is estimated that that 20% of patients receiving MBS item 38387 in 2014 would be NYHA class II patients eligible to receive CRT-D. Therefore, it is estimated that 183 new patients would be treated with CRT-D in 2014 increasing to 242 patients in 2018. A sensitivity analysis is presented in which 10% and 40% of patients receiving MBS item 38387 receive CRT-D.

Table E-2 Predicted number of patients treated with CRT-D

Description	Year 1	Year 2	Year 3	Year 4	Year 5
	2014	2015	2016	2017	2018
Number of private patients receiving ICD	916	989	1062	1135	1208
Proportion private patients receiving ICD expected to receive CRT-D	20%	20%	20%	20%	20%
Number of private patients receiving ICD expected to receive CRT-D	183	198	212	227	242
Total number of private patients receiving CRT-D	183	198	212	227	242

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator

E.3 ESTIMATED EXTENT OF CHANGES IN USE OF OTHER THERAPEUTIC MEDICAL SERVICES

As described above, it is expected that all NYHA class II patients receiving CRT-D would otherwise receive ICD. Therefore, in the scenario in which CRT-D is not reimbursed (i.e. world without CRT-D), all patients receive ICD.

E.4 COSTS OF CRT-D AND ICD

For the financial impact analysis, the costs for each treatment are separated into MBS costs, PBS costs, private hospital costs and private health insurance prosthesis costs. For CRT-D and ICD, the costs associated with surgery are included. MBS costs associated with ongoing maintenance of the devices (e.g. monitoring costs) are expected to be the similar for ICD and CRT-D and are not included in this section. Patients receiving ICD and CRT-D through the MBS are private patients. Therefore, hospital and device costs for these patients would be covered privately by private health insurance companies and not by any State or Federal government health budgets. Further discussion of the unit costs included for CRT-D implant and ICD is presented in Section D of this submission.

E.4.1 MBS costs

The MBS costs for CRT-D and ICD are presented in **Table E-3**. The total MBS costs are $1,520.79 for CRT-D and $1,116.83 for ICD placement.

Table E-3 MBS costs for CRT-D and ICD

Description	Unit price ($)	Quantity (no.)	Percentage of fee claimable under MBS Multiple Services Rule	Cost	Source
CRT-D implantation					
Insertion of LV lead (transvenous)	$1,224.60	0.937	100%	$1,147.45	MBS item 38368
Insertion of LV lead (thoracotomy)	$1,224.60	0.063	100%	$77.15	MBS item 38654
Insertion of RA and RV leads	$1,052.65	1	50%	$526.33	MBS item 38384
Insertion of RA pacemaker leads	$638.65	1	25%	$159.66	MBS item 38350
Insertion of CRT-D device	$287.75	1	25%	$71.94	MBS item 38371
Average cost of general anaesthesia (as reported in DAP)	$226.00	0.2	100%	$45.20	MBS items 17610, 20410, 21941, 25000, 25015, 23021, 23101
Total treatment costs for CRT-D					*$2,027.73*
Total MBS costs for CRT-D (75% benefit)					***$1,520.79***
ICD implantation					
Insertion of RA and RV leads	$1,052.65	1	100%	$1,052.65	MBS item 38384
Insertion of RA pacemaker leads	$638.65	1	50%	$319.33	MBS item 38350
Insertion of ICD device	$287.75	1	25%	$71.94	MBS item 38387
Average cost of general anaesthesia (as reported in DAP)	$226.00	0.2	100%	$45.20	MBS items 17610, 20410, 21941, 25000, 25015, 23021, 23101
Total treatment costs for ICD					***$1,489.11***
Total MBS costs for ICD (75% benefit)					***$1,116.83***

NB. Rounding applies

Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; DAP, decision analytical protocol; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MBS, Medicare Benefits Schedule; RA, right atrial; RV, right ventricular

E.4.2 PBS costs

All patients receiving ICD and CRT-D receive OMT. The drug regimen for ICD and CRT-D is assumed to be similar (see Section D). This is a conservative assumption as there is evidence that CRT-D may reduce OMT costs. However, these costs are likely to be modest and are not captured in this analysis.

E.4.3 State government costs

Patients receiving ICD and CRT-D through the MBS are private patients. Therefore, hospital costs for these patients would be covered privately by private health insurance companies and not by any State or Federal government health budget.

E.4.4 Private hospital costs

Private hospital costs (excluding prosthesis costs) for CRT-D is $5,388.03 and for ICD is $4,864.10 (**Table E-4**).

Table E-4 Private hospital costs for CRT-D and ICD

Description	Unit price ($)	Weighting (%)	Cost
CRTD hospital costs			
Hospital costs procedure without complications (Source: Private VERSION 5.1 Round 13 (2008-2009) Cost AR-DRG F01B; Weighting RAFT trial see Section B.6.3)	$4315.00	86.7%	$3,741.61
Hospital costs procedure with complications (Source: Private VERSION 5.1 Round 13 (2008-2009) Cost AR-DRG F01A; Weighting RAFT trial see Section B.6.3)	$12,390.00	13.3%	$1,646.42
Total weighted average CRT-D hospital costs (excluding prosthesis costs)			***$5,388.03***
ICD hospital costs			
Hospital costs procedure without complications (Source: Private VERSION 5.1 Round 13 (2008-2009) Cost AR-DRG F01B; Weighting RAFT trial see Section B.6.3)	$4315.00	93.2%	$4021.89
Hospital costs procedure with complications (Source: Private VERSION 5.1 Round 13 (2008-2009) Cost AR-DRG F01A; Weighting RAFT trial see Section B.6.3)	$12,390.00	6.8%	$841.64
Total weighted average ICD hospital costs (excluding prosthesis costs)			***$4,864.10***

NB. Rounding applies
Abbreviations: AR–DRG, Australian Refined Diagnosis Related Groups; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator

E.4.5 Cost of devices

The cost of the CRT-D and ICD devices are included on the prostheses list. Therefore, the cost of the devices would be covered by private health insurance companies and not by any State or Federal government health budget. Device costs for private patients are $67,415.23 for CRT-D and $57,071.69 for ICD.

Table E-5 Prostheses list costs for CRT-D and ICD

Description	Unit price ($)	Quantity (no.)	Cost
CRT-D prostheses costs			
CRT-D generator (successful implantation)	$51,141.76	0.947	$48,434.94
ICD generator (where a CRTD cannot be placed)	$46,808.89	0.0529	$2,477.50
LV lead	$6,240.00	1	$6,240.00
Defibrillation lead	$9,000.00	1	$9,000.00
Pacemaker lead	$1,262.80	1	$1,262.80
Total CRT-D prostheses costs			***$67,415.23***
ICD prostheses costs			
ICD generator	$46,808.89	1	$46,808.89
Defibrillation lead	$9,000.00	1	$9,000.00
Pacemaker lead	$1,262.80	1	$1,262.80
Total ICD prostheses costs			***$57,071.69***

NB. Rounding is applied
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, implantable cardioverter-defibrillator; LV, left ventricular

E.5 ESTIMATED FINANCIAL IMPLICATIONS FOR THE MBS

E.5.1 Cost to MBS in world without CRT-D

The cost to the MBS in the world without CRT-D is $204,513 in 2014, which is expected to increase to $269,787 in 2018 (**Table E-6**).

Table E-6 Cost to MBS in world without CRT-D

Description	2014	2015	2016	2017	2018
Number of patients treated with ICD	183	198	212	227	242
Cost of ICD per patient	$1,117	$1,117	$1,117	$1,117	$1,117
Total cost of ICD	**$204,513**	**$220,831**	**$237,150**	**$253,468**	**$269,787**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; ICD, Implantable cardioverter defibrillator; MBS, Medicare Benefits Schedule

E.5.2 Cost to MBS in world with CRT-D

The cost to the MBS in the world with CRT-D is $278,485 in 2014, which is expected to increase to $367,369 in 2018 (**Table E-7**).

Table E-7 Cost to MBS in world with CRT-D

Description	2014	2015	2016	2017	2018
Number of patients treated with CRT-D	183	198	212	227	242
Cost of CRT-D per patient	$1,521	$1,521	$1,521	$1,521	$1,521
Total cost of CRT-D	**$278,485**	**$300,706**	**$322,927**	**$345,148**	**$367,369**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; MBS, Medicare Benefits Schedule

E.5.3 Net financial impact to the MBS

The net financial impact to the MBS is $73,972 in 2014 which is expected to increase to $97,582 in 2018 (**Table E-8**).

Table E-8 Net Cost to MBS

Description	2014	2015	2016	2017	2018
Total cost in world with CRT-D	$278,485	$300,706	$322,927	$345,148	$367,369
Total cost in world without CRT-D	$204,513	$220,831	$237,150	$253,468	$269,787
Net total cost to MBS	**$73,972**	**$79,875**	**$85,777**	**$91,680**	**$97,582**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; MBS, Medicare Benefits Schedule

E.6 ESTIMATED FINANCIAL IMPLICATIONS FOR GOVERNMENT HEALTH BUDGETS

E.6.1 Net financial impact to the PBS

As discussed above, all patients receiving ICD and CRT-D receive OMT. The drug regimen for ICD and CRT-D is assumed to be the same. Therefore, there are not expected to be additional costs to the PBS.

E.6.2 Net implications for state government health budgets

As discussed above, patients receiving ICD and CRT-D through the MBS are private patients. Therefore, hospital costs for these patients would be covered by private health insurance companies and not by any State or Federal government health budget.

E.6.3 Net implications for private hospitals

The net financial impact to private hospitals is $96,114 in 2014 which is expected to increase to $126,791 in 2018 (**Table E-9**).

Table E-9 Net Cost to private hospitals

Description	2014	2015	2016	2017	2018
Total cost in world with CRT-D	$986,819	$1,065,559	$1,144,300	$1,223,041	$1,301,781
Total cost in world without CRT-D	$890,705	$961,776	$1,032,848	$1,103,919	$1,174,991
Net total cost to private hospitals	**$96,114**	**$103,783**	**$111,452**	**$119,122**	**$126,791**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation

E.6.4 Net implications for prostheses list

The net financial impact to the prostheses list is $1,894,090 in 2014 which is expected to increase to $2,498,626 in 2018 (**Table E-10**).

Table E-10 Net Cost to prostheses list

Description	2014	2015	2016	2017	2018
Total cost in world with CRT-D	$12,344,949	$13,329,982	$14,315,015	$15,300,048	$16,285,081
Total cost in world without CRT-D	$10,450,859	$11,284,758	$12,118,657	$12,952,556	$13,786,455
Net total cost to prostheses list	**$1,894,090**	**$2,045,224**	**$2,196,358**	**$2,347,492**	**$2,498,626**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation

E.6.5 Net implications for healthcare

The overall net financial impact to healthcare is presented in **Table E-11**. The net financial impact to healthcare is $2,064,177 in 2014 which is expected to increase to $2,722,999 in 2018. The device costs incurred by private health insurers accounts for approximately 90% of the total net financial impact of reimbursing CRT-D in the newly proposed MBS indication.

Table E-11 Net Cost to healthcare

Description	2014	2015	2016	2017	2018
Net cost to the MBS	$73,972	$79,875	$85,777	$91,680	$97,582
Net cost to private hospitals	$96,114	$103,783	$111,452	$119,122	$126,791
Net cost to private insurers through prostheses list	$1,894,090	$2,045,224	$2,196,358	$2,347,492	$2,498,626
Net total cost to healthcare	**$2,064,177**	**$2,228,882**	**$2,393,588**	**$2,558,293**	**$2,722,999**

NB. Rounding applies
Abbreviations: MBS, Medicare Benefits Schedule

E.7 IDENTIFICATION, ESTIMATION AND REDUCTION OF UNCERTAINTY

E.7.1 Number of patients receiving CRT-D

In the base-case analysis, it was estimated that 20% of patients receiving ICD through MBS item 38387 would receive CRT-D. To estimate the percentage of patients that would receive CRT-D, seven KOLs were asked to estimate the proportion of patients that are currently eligible to receive MBS item 38387 that would meet the criteria to receive CRT-D (NYHA class II patients with a LVEF of less than or equal to 30%, and a QRS duration of 150 ms or more). Responses ranged from 10% to less than 40%, with 20% the most common response. Therefore, 20% was used in the base case. For this analysis, the proportion of patients receiving MBS item 38387 that would receive CRT-D if it were reimbursed was increased to the upper range of response (40%) (**Table E-12**) and decreased to the lower range of response (10%) (**Table E-13**).

The net financial impact to the MBS of increasing the percentage of patients receiving CRT-D to 40% is $147,945 in 2014 which is expected to increase to $195,164 in 2018.

Table E-12 Financial impact of increasing the number of patients receiving CRT-D

Description	2014	2015	2016	2017	2018
Total cost in world with CRT-D	$556,970	$601,412	$645,854	$690,296	$734,737
Total cost in world without CRT-D	$409,025	$441,662	$474,299	$506,936	$539,574
Net total cost to MBS	**$147,945**	**$159,749**	**$171,554**	**$183,359**	**$195,164**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; MBS, Medicare Benefits Schedule

The net financial impact to the MBS of decreasing the percentage of patients receiving CRT-D to 10% is $36,986 in 2014 which is expected to increase to $48,791 in 2018.

Table E-13 Financial impact of decreasing the number of patients receiving CRT-D

Description	2014	2015	2016	2017	2018
Total cost in world with CRT-D	$139,242	$150,353	$161,463	$172,574	$183,684
Total cost in world without CRT-D	$102,256	$110,416	$118,575	$126,734	$134,893
Net total cost to MBS	**$36,986**	**$39,937**	**$42,889**	**$45,840**	**$48,791**

NB. Rounding applies
Abbreviations: CRT-D, cardiac resynchronisation therapy device capable of defibrillation; MBS, Medicare Benefits Schedule

APPENDIX 1: CRT-D GENERATORS AND LEADS INCLUDED ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

Table A CRT-D generators and leads included on the Australian Register of Therapeutic Goods

Sponsor's name	Manufacturers name	Device	ARTG number
CRT-D generators			
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Lumax 540 HF-T	153974
		Lumax 740 HF-T	195225
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	COGNIS 100 HE DF1/IS1	154033
		COGNIS 100 HE DF1/LV1	154034
		COGNIS 100 HE GDT LLHH	154035
		ENERGEN CRT-D - Model N142	192553
		ENERGEN CRT-D - Model N143	192554
		INCEPTA CRT-D - Model N162	192555
		INCEPTA CRT-D - Model N163	192556
		INCEPTA CRT-D - Model N165	192557
		PUNCTUA CRT-D – Model N052	193179
		PUNCTUA CRT-D – Model N053	193180
Medtronic Australasia Pty Ltd	Medtronic Inc	Concerto II CRT-D Model D294TRK	162425
		Consulta CRT-D Model D234TRK	154089
		Consulta CRT-D D 214TRM	185553
		MAXIMO II CRT-D D264TRM	190851
		Maximo II CRT-D Model D284TRK	154092
		Protecta XT CRT-D D354TRM	181996
		Protecta XT CRT-D D354TRG	176435
		Protecta CRT-D Model D364TRG	176439
		Protecta CRT-D DF 4 D364TRM	202451
		VIVA XT CRT-D DTBA2D1	203212
		VIVA XT CRT-D DTBA2D4	203211
		VIVA S CRT-D DTBB2D1	203210
		VIVA S CRT-D DTBB2D4	203209
		Viva Quad S CRT-D DTBB2QQ	203841
		Viva Quad XT CRT-D DTBA2QQ	203840
		Brava CRT-D – Model DTBC2D4	203842
		Brava CRT-D – Model DTBC2D1	203843
		Brava Quad CRT-D – Model DTBC2QQ	203844
Sorin Group Australia	Sorin Biomedica Crm Srl	Paradym CRT 8750	163470
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Atlas II HF Model V-365	136216
		Promote Accel RF Model CD3215	158920
		Promote Accel Model CD3215-36Q	170537
		Promote Quadra CD3237-40	181842
		Promote Quadra CD3237-40Q	181843
		Promote Quadra CD3239-40	184879
		Promote Quadra CD3239-40Q	184880
		Unify CRT-D CD3235-40Q	171540
		Unify CRT-D CD3235-40	171541

Sponsor's name	Manufacturers name	Device	ARTG number
		Unify Quadra CD3251-40	186715
		Unify Quadra CD3251-40Q	186716
		Unify Quadra MP CD3255	193896
		Unify Assura CD3261-40	198823
		Quadra Assura CD3267-40	198824
		Unify Assura CD3261-40Q	202933
		Quadra Assura CD3267-40Q	202939
		Quadra Assura CD3367-40	207160
		Quadra Assura CD3367-40Q	207161
		Quadra Assura CD3367-40C	207159
		Quadra Assura CD3367-40QC	207162
		Quadra Assura MP CD3371-40	207163
		Quadra Assura MP CD3371-40Q	207156
		Quadra Assura MP CD3371-40C	207157
		Quadra Assura MP CD3371-40QC	207158
		Unify Assura CD3361-40	207200
		Unify Assura CD3361-40Q	207198
		Unify Assura CD3361-40C	207199
		Unify Assura CD3361-40QC	207190
ICD, pacemaker and left ventricular electrode leads			
Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Corox OTW xx-UP Steroid	119415
		Corox OTW (-S) xx-BP	142124
		Corox OTW -L BP	174958
		Dextrus Model 413x	140309
		Linox SD xx/yy	129076
		Linox TD xx/yy	132892
		Linox S xx	142174
		Linox T xx	142175
		Linox Smart SD xx/yy	167216
		Linox Smart TD xx/yy	167217
		Linox smart S DX - Lead,	191636
		Myopore Bipolar Sutureless Myocardial Pacing Lead	159391
		MYOPORE Bipolar Sutureless Myocardial Pacing Lead	194595
		Selox ST xx	118361
		Selox JT xx	118362
		Siello S xx	170066
		Siello T xx	170067
		Siello JT xx	170068
		Safio S	188217
		Setrox S xx	129077
Boston Scientific Pty Ltd	Cardiac Pacemakers Inc	ACUITY Models 4554,4555,4556	126935
		Acuity Spiral Lead	155274
		EASYTRAK IS-1	112809
		EASYTRAK 3	114811
		EASYTRAK 3 IS-1	119321
		Easytrak 2	99579
		EASYTRAK 2 IS-1	112810
		Endotak Reliance G Passive Fixation Leads model 0174-0177	116534
		Endotak Reliance SG Passive Fixation Leads models 0170-0173	116535
		ENDOTAK RELIANCE SG LEADS	119322

Sponsor's name	Manufacturers name	Device	ARTG number
		ENDOTAK RELIANCE G LEADS	119328
		Endotak Reliance Leads models 0147,0148,0149	128708
		Endotak Reliance S Passive Fixation Implantable Lead	165638
		Endotak Reliance Active Fixation Implantable Lead	165639
		Endotak Reliance S Active Fixation Implantable Lead	165640
		Endotak Reliance G Passive Fixation Implantable Lead	165641
		Endotak Reliance SG Passive Fixation Implantable Lead	165642
		Endotak Reliance Passive Fixation Implantable Lead	165643
		Endotak Reliance G Active Fixation Implantable Lead	165644
		Endotak Reliance SG Active Fixation Implantable Lead	165645
		Endotak SQ Array XP Model 0085	128625
		Fineline II Sterox Leads	128060
		Flextend Models 4086, 4087, 4088	129949
		Myopore Bipolar Sutureless Myocardial Pacing Lead	161123
		Selute; Model 4185	128826
		Selute Picotip VDD	128827
		Selute Picotip Atrial J	128828
		Selute Picotip; Model 4035	128965
Medtronic Australasia Pty	Medtronic Inc	5071 - Sutureless, unipolar, myocardial screw-in pacing lead	136181
		Attain OTW Model 4194 Lead	120254
		Attain StarFix Model 4195	131306
		Attain Ability 4196	151600
		Attain Ability Plus Model 4296	178071
		Attain Ability Straight Model 4396	178072
		Capsure Fix Novus Lead	134286
		Capsure SP Novus Leads	134288
		Capsure Sense Leads	134289
		Capsure Sense Lead - Model 4074	134331
		Capsure Sense Lead - Model 4574	134426
		Capsure Z Novus Model 5554	142167
		Capsure Z Novus Model 5054	142168
		Capsure SP Novus Model 5092	142170
		Capsure VDD-2 Model 5038	142171
		Capsure Epi Lead - Model 4965	134427
		Capsure Epi Leads	134287
		CapsureFix Model 5568	142169
		CapsureFix Novus Model 4076	159822
		CapsureFix MRI Model 5086MRI	165256
		Epicardial Patch 6721	136183
		Implantable Subcutaneous Defibrillator Lead 6996SQ	132315
		SelectSecure Model 3830	131307
		Sprint Quattro Secure	134290
		Sprint Quattro Model 6944	142172
		Sprint Quattro Secure S Model 6935	157536
		SPRINT QUATTRO SECURE Model 6947M DSP	191092
		SPRINT QUATTRO SECURE Model 6947M DXAC/DSP	191093
		Transvene SVC Lead Model 6937	136182
Pacing Importers Pty Ltd	Oscor Inc	Refino ER	196633
		Refino ERJU	196835
		Refino ERU	196836

Sponsor's name	Manufacturers name	Device	ARTG number
Sorin Group Australia	ELA Medical	Petite ER	178088
		Petite ERJB	178409
		Physique ER	178090
		PY2 ERU	178083
		Refino ERU	178089
		Refino ERJU	178410
St Jude Medical Australia Pty Ltd	St Jude Medical Cardiac Rhythm Management Division USA	Durata Lead Model 7120	159843
		Durata Lead Model 7171	159844
		Durata Lead Model 7121	159845
		Durata Lead Model 7122	159846
		Durata Lead Model 7131	159847
		Durata Lead Model 7130	159848
		Durata Lead Model 7170	159849
		Durata Lead model 7120Q	170589
		Durata Lead model 7121Q	170590
		Durata Lead model 7122Q	170591
		Durata Lead model 7170Q	170592
		Durata Lead model 7171Q	170593
		Durata Lead model 7172Q	170594
		IsoFlex Lead Model 1944	159532
		IsoFlex Lead Model 1948	159533
		MRI Conditional Tendril Lead LPA1200M	193132
		Myodex Lead Model 1084T	145900
		OptiSense Lead Model 1999	159534
		QuickFlex Lead Model 1258T	161391
		QuickFlex XL 1158T	153165
		QuickFlex Lead 1156T	153166
		QuickSite Lead Model 1056K	120366
		Quartet Model 1458Q Lead	171332
		Tendril SDX Pacing Lead Model 1688TC	116571
		Tendril ST Model 1882TC Lead	143300
		Tendril ST Model 1888TC Lead	143301
		Tendril STS Lead Model 2088TC	170587

Source: Australian Register of Therapeutic Goods: http://www.tga.gov.au/industry/artg-searching.htm

APPENDIX 2: CRT-D GENERATORS AND LEADS INCLUDED ON THE PROSTHESES LIST

Table B CRT-D generators and leads include on the Prostheses List

Sponsor	Billing code	Product name	Description	Min benefit ($)
CRT-D generators				
Cardiac Prostheses Group 8.3.1 - Dual Chamber, Bivent pacing, Vent tachyarrhythmia treatment, programming enabling variation L vent & R vent stimulation timing & independent outputs				
Biotronik Australia Pty Ltd	BT102	Lumax 540 HF-T	High Energy, Three Chamber ICD (Implantable Cardiac Defibrillator) with Advanced Patient Management Via unique Home Monitoring Technology incorporating Automatic RV/LV Threshold Monitoring and Extended Longevity.	47,840.00
	BT128	Lumax 740 HF-T	CRT-ICD with 40J output with Advanced Patient Management, Home Monitoring, automatic right and left ventricular Threshold Monitoring and Extended Longevity	47,840.00
Boston Scientific Australia Pty Ltd	BS138	COGNIS 100 HE 4-SITE	CRT-D high energy with RF IS4	48,590.00
	BS139	COGNIS 100 HE (DF-1/IS-1 & DF-1/LV-1)	CRT-D high energy with RF	47,840.00
	BS202	ENERGEN DF-4 CRT-D	High energy CRT-D with DF-4 RV connector and IS-1 LV connector	48,590.00
	BS203	ENERGEN CRT-D	High energy CRT-D with DF-1 RV connector and IS-1 LV connector	47,840.00
	BS205	INCEPTA DF-4 CRT-D	High energy CRT-D with DF-4 RV connector and lS-1 LV connector	48,590.00
	BS209	INCEPTA CRT-D	High energy CRT-D with DF-1 RV connector & lS-1 (N163) or LV-1 (N165) LV connector	47,840.00
Cardiac Prostheses Group 8.3.2 - Features of 8.3.1 plus auto test sensing parameters, auto capture threshold test, lead impedance test, wireless remote analysis				
Medtronic Australasia Pty Ltd	MC812	Consulta CRT-D Model D234TRK	Fully Automatic, Wireless Implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT), and therapies for ventricular and atrial tachyarrhythmia	52,000.00
	MC983	Consulta CRT-D Model D214TRM	Fully Automatic, Wireless Implantable cardioverter defribillator with cardiac resynchronization therapy (CRT), and therapies for ventrilcular and atrial tachyarrhythmia. DF-4 lead connector.	52,750.00
	MI017	Protecta XT CRT-D D354TRG	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF-1)	52,000.00
	MI026	Protecta XT CRT-D D354TRM	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF-4)	52,750.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
	MI069	VIVA XT CRT-D DTBA2D1	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring, Complete Capture Management Specifications (DF1), and AdaptivCRT	52,000.00
	MI070	VIVA XT CRT-D DTBA2D4	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Technology, OptiVol 2.0 Fluid Status Monitoring, Complete Capture Management Specifications (DF4), and AdaptivCRT	52,750.00
	MI071	VIVA S CRT-D DTBB2D1	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Tehnology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF1)	52,000.00
	MI072	VIVA S CRT-D DTBB2D4	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, SmartShock Tehnology, OptiVol 2.0 Fluid Status Monitoring and Complete Capture Management Specifications (DF4)	52,750.00
Sorin Group Australia Pty Ltd	SA145	PARADYM CRT-D 8750	Implantable Cardioverter Defibrillator with Cardiac Resynchronisation therapy, High Energy	47,840.00
	SA158	PARADYM RF CRT-D 9750	Implantable Cardioverter Defibrillator, for resyncronisation of heart failure, high output extended longevity and home monitoring.	52,000.00
	SA159	PARADYM RF CRT-D SonR 9770	Implantable Cardioverter Defibrillator for resyncronisation of heart failure, high output, extended longevity and home monitoring, and in conjunction with a dedicated atrial lead with SonR sensor provides automatic adjustment of AV/VV delays for optimisation of resynchronisation therapy.	52,000.00
St Jude Medical Australia Pty Ltd	SJ145	Promote Accel CD3215-30	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry	49,760.00
	SJ150	Promote Accel RF CD3215-36	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry	52,000.00
	SJ236	Promote Accel CD3215-36Q	Cardiac Resynchronisation Therapy Defibrillator with RF Telemetry and SJ4 connector	52,750.00
	SJ244	Unify CRT CD3235-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and SJ4 connector	52,750.00
	SJ246	Unify CRT CRT CD3235-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy	52,000.00
	SJ252	Promote Quadra CRT CD3239-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration and SJ 4 connector	52,750.00
	SJ253	Promote Quadra CRT CD3239-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration	52,000.00
	SJ271	Unify Quadra CRT CD 3251-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered plus Quadripolar pacing	52,000.00
	SJ272	Unify Quadra CRT CD 3251-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy with quadripole pacing and SJ4 connector	52,750.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
	SJ281	Promote Quadra CRT CD3237-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy, VectSelect Quartet Programmable LV pulse configuration and Multisite Pacing	52,000.00
	SJ282	Promote Quadra CD3237-40Q	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered energy and VectSelect Quartet Programmable LV pulse configuration plus Multisite Left Ventricular Pacing and SJ4 connector.	52,750.00
	SJ298	Quadra Assura CD3267-40	Cardiac Resynchronisation Therapy Defibrillator with 40J delivered and Multisite Left Ventricular Pacing and Quadripolar pacing	52,000.00
	SJ301	Unify Assura CD3261-40	Cardiac Resynchronisation Therapy Defribrillator with 40J delivered energy	52,000.00
	SJ312	Quadra Assura CD3267-40Q	Cardiac Resynchronisation Therapy Defribrillator with 40J delivered energy, Multisite Left Ventricular Pacing plus Quadripolar pacing and SJ4 connector	52,750.00
	SJ314	Unify Assura CD3261-40Q	Cardiac Resynchronisation Therapy Defribrillator with 40J delivered energy and SJ4 connector	52,750.00
ICD leads				
Cardiac Prostheses Group 7.7.5 *- Transvenous/steroid/passive leads*				
Biotronik Australia Pty Ltd	BT092	Linox TD	Fractal and steroid coated passive fixation quadripolar ICD lead	9,000.00
	BT093	Linox T	Single-shock coil ICD lead with passive fixation	9,000.00
	BT119	Linox SMART TD	Dual-shock coil ICD lead with passive fixation and hydrophilic coating on lead body	9,000.00
	BT137	VIGILA 1 CT	Single-shock coil ICD lead with passive fixation	9,000.00
Boston Scientific Australia Pty Ltd	BS170	Endotak Reliance S 4-SITE	Passive fixation single coil defibrillation leads & 4-SITE connector	9,000.00
	BS180	Endotak Reliance G 4-SITE	Passive fixation dual coil defibrillation leads with ePTFE covered coils & 4-SITE connector	9,000.00
	BS181	Endotak Reliance SG 4-SITE	Passive fixation single coil defibrillation leads with ePTFE covered coil & 4-SITE connector	9,000.00
	BS183	Endotak Reliance 4-SITE	Passive fixation dual coil defibrillation leads with 4-SITE connector	9,000.00
Guidant Australia Pty Ltd	GU115	Endotak Reliance Lead	Passive Dual Coil	9,000.00
	GU158	Endotak Reliance SG Passive	Passive Single Coil with GORE ePTFE covered coil	9,000.00
	GU159	Endotak Reliance G Passive	Passive Dual Coil with GORE ePTFE covered coil	9,000.00
Medtronic Australasia Pty Ltd	MC002	Medtronic Sprint Quattro Lead Model 6944RV/SVC 65cm; Model 6944RV/SVC 75cm; or Model 6944RV/SVC 100cm; Medtronic Sprint Quattro Lead Model 6944RV/SVC 58cm	Silicone and polyurethane	9,000.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
St Jude Medical Australia Pty Ltd	SJ158	Durata 7170, 7171	Passive fixation, true bipolar, dual coil, steroid eluting, endocardial defibrillation leads with Optium insulation overlay	9,000.00
	SJ245	Durata 7170Q, 7171Q and 7172Q	7170Q/7171Q - passive fixation, bipolar, dual coil, 7172Q - passive fixation, bipolar - single coil steroid eluting endocardial defibrillation leads with Optim insulation overlay and SJ4 quadripolar lead connector	9,000.00
Cardiac Prostheses Group 7.7.6 - Transvenous/steroid/active leads				
Biotronik Australia Pty Ltd	BT084	Linox SD	Fractal coated and steroid electrode, active fixation quadrapolar	9,000.00
	BT096	Linox S	Active fix RV bipolar fractal coated steroid IC lead	9,000.00
	BT120	Linox SMART SD	Dual-shock coil ICD lead with active fixation helix and hydrophilic coating on lead body	9,000.00
	BT125	Linox SMART SD X	LinoxSmart S DX pentapolar, singlecoil ICD lead with floating atrial dipole. Permanent, transvenous implantation in the right ventricle.	9,000.00
	BT134	VIGILA 2 CR	Fractal coated and steroid electrode, active fixation quadrapolar	9,000.00
	BT140	VIGILA 1 CR	Single shock coil ICD lead with active fixation, fractal coating and steroid elution	9,000.00
	BT142	VIGILA 2 CT	Fractal coated and steroid electrode, active fixation, quadrapolar	9,000.00
Boston Scientific Australia Pty Ltd	BS174	Endotak Reliance SG 4-SITE	Active fixation single coil defibrillation leads with ePTFE covered coil & 4-SITE connector.	9,000.00
	BS178	Endotak Reliance 4-SITE	Active fixation dual coil defibrillation leads with 4-SITE connector	9,000.00
	BS179	Endotak Reliance S 4-SITE	Active fixation single coil defibrillation leads & 4-SITE connector	9,000.00
	BS182	Endotak Reliance G 4-SITE	Active fixation dual coil defibrillation leads with ePTFE covered coils & 4-SITE connector	9,000.00
Guidant Australia Pty Ltd	GU163	ENDOTAK RELIANCE G Active	Active Dual Coil with GORE ePTFE covered coils	9,000.00
	GU164	ENDOTAK RELIANCE SG Active	Active Single coil with GORE ePTFE covered coils	9,000.00
Medtronic Australasia Pty Ltd	MC208	Medtronic Sprint Quattro Secure Lead Model 6947 58cm; Model 6947 65cm; Model 6947 75cm; Model 6947 100cm	Leads, Defibrillator, Implantable, Silicone, polyurethane, platinised tantalum coils, steroid eluting tip	9,000.00
	MC834	Sprint Quattro Secure S	Model 6935, Active Fixation Single Coil Defibrillation Lead	9,000.00
	MI033	Sprint Quattro Secure 6947M Lead	Active fixation, true bipolar, dual coil defibrillation leads with silicone backfill and DF-4 connector	9,000.00
St Jude Medical Australia Pty Ltd	SJ157	Durata 7120, 7121, 7122, 7130, 7131	Active fixation bipolar, dual-coil/single coil Steroid-eluting Endocardial Defibrillation Leads	9,000.00
	SJ230	Durata 7120Q, 7121Q and 7122Q	7120/1Q - Active fixation, true bipolar; 7122Q - Active fixation true bipolar - single coil steroid eluting endocardial defibrillation leads with Optim insulation overlay and SJ4 quadripolar lead connector	9,000.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
Left ventricular leads				
***Cardiac Prostheses Group 8.8.11** - Transvenous, Multi-Polar, Passive, Steroid, Left Ventricular*				
Biotronik Australia Pty Ltd	BT095	Corox OTW BP; Corox OTW-S BP	Bipolar, steroid eluting coronary sinus pacing lead with fractal coating	6,240.00
	BT121	Corox OTW-L BP	Corox OTW-L BP is a bipolar coronary sinus lead, intended for permanent implantation in the venous system and left ventricular pacing with appropriate single or multi chamber cardiac pacemakers or ICDs as part of cardiac resynchornisation therapy (CRT)	6,240.00
	BT135	CELERITY PILOT	Bipolar, steroid eluting coronary sinus pacing lead with fractal coating	6,240.00
	BT136	CELERITY 2D, CELERITY 3D	Bipolar, steroid eluting coronary sinus pacing lead with fractal coating. 2D preshaped curved distal end; 3D preshaped helix distal end	6,240.00
Guidant Australia Pty Ltd	GU138	Easytrak 2, Model 4514, 4515, 4516, 4517, 4518, 4519, 4520	Bipolar, passive fixation	6,240.00
	GU153	Easytrak 2 Is-1 Lead - Models 4542, 4543 & 4544	Bipolar, passive fixation	6,240.00
	GU156	Easytrak 3 Lead - Models 4521, 4522, 4523, 4524, 4525, 4526 and 4527	Bipolar, passive fixation	6,240.00
	GU162	Easytrak 3 IS-1 Lead	Bipolar, passive fixation	6,240.00
	GU165	Acuity Steerable Lead	Bipolar, passive fixation	6,240.00
Medtronic Australasia Pty Ltd	MC699	Attain OTW Model 4194 Lead	Model 4194	6,240.00
	MC811	Attain Ability 4196 LV Lead	Over the wire dual electrode left ventricular lead	6,240.00
	MI013	Attain Ability Plus 4296	Over the wire electrode left ventricular lead	6,240.00
	MI014	Attain Ability Straight 4396	Over the wire dual left ventricular lead	6,240.00
St Jude Medical Australia Pty Ltd	SJ208	Quick Flex µ 1258T	4F Bipolar Left Ventricular Pacing Lead	6,240.00
	SJ243	Quartet 1458Q	Quadripolar, Left Ventricular Pacing Lead with Optim Lead Insulation	6,240.00
Pacemaker leads				
Cardiac Prostheses Group 8.8.8 - Transvenous, Bi-Polar, Passive, Steroid, Right Ventricular/Atrial				
Biotronik Australia Pty Ltd	BT066	Selox ST	Transvenous Bipolar Passive Steroid Ventricular Pacing Lead, fractal coated	1,248.00
	BT067	Selox JT	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixation lead that carries a J-shaped distal end	1,248.00
	BT117	Siello JT	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixationlead that carries a J-shaped distal end	1,248.00
	BT118	Siello T	Sub 6F, steroid-eluting, transvenous, endocardial, bipolar passive-fixation lead	1,248.00
	BT138	TILDA T	Bipolar, passive fixation, steroid eluting pacing lead with fractal coating	1,248.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
	BT141	TILDA JT	Bipolar, passive fixation, steroid eluting pacing lead with fractal coating and J-shape	1,248.00
Guidant Australia Pty Ltd	GU009	Fineline II Sterox IROX Lead	Bipolar passive fixation	1,248.00
	GU011	Fineline II Sterox IROX Lead	Bipolar passive fixation	1,248.00
	GU012	Fineline II Sterox IROX Lead	Bipolar, passive fixation	1,248.00
	GU028	Guidant Aust Selute Picotip VDD Lead	VDD bipolar, passive fixation	1,544.00
Medtronic Australasia Pty Ltd	MC010	Medtronic Capsure SP Novus Model 5092	Bipolar, steroid, passive fixation pacing lead	1,248.00
	MC229	Medtronic Capsure SP Novus Model 5594 Lead	Bipolar, steroid, passive fixation pacing lead	1,248.00
	MC336	Medtronic Capsure Z Novus Model 5054 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00
	MC337	Medtronic Capsure Z Novus Model 5554 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00
	MC372	CapSure Sense pacemaker lead Models 4074 & 4574	Bipolar, steroid, passive fixation pacing lead	1,248.00
	MC052	Medtronic Capsure VDD2 Model 5038 AV Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,544.00
Pacing Importers Pty Ltd - Life Systems	PI023	Refino ER Series	Passive fixation, bi-polar, permanent pacing leads with a steroid eluting ring	1,248.00
Sorin Group Australia Pty Ltd	SA152	Refino ER Series	Steroid eluting passive fixation pacing lead. Permanent pacing lead, Model Refino ER, is indicated for the pacing and sensing of the ventricle. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker). Permanent pacing leads, Models Refino ERJ and ERJU are indicated for the pacing and sensing of the atrium. This permanent pacing lead is used in conjunction with and IS-1 compatible implantable pulse generator (pacemaker).	1,248.00
	SA154	Petite ER Series	Steroid eluting passive fixation pacing lead. Permanent pacing lead, Petite ER series, is indicated for the pacing and sensing of the ventricle. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker). Permanent pacing lead, Petite ERJ series, is indicated for the pacing and sensing of the atrium. This permanent pacing lead is used in conjunction with an IS-1 compatible implantable pulse generator (pacemaker).	1,248.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
St Jude Medical Australia Pty Ltd	SJ146	Isoflex 1944T & 1948T	Passive-Fixation, Bipolar, Steroid Eluting, Endocardial Pacing Lead with Optim insulation	1,248.00
Cardiac Prostheses Group 8.8.9 - Transvenous, Bi-Polar, Active, Steroid, Right Ventricular/Atrial				
Biotronik Australia Pty Ltd	BT083	Setrox S	Bipolar active fixation lead with fractal coated and steroid eluting electrode	1,248.00
	BT097	Dextrus (marketed by Boston Scientific)	Bipolar, silicone, active fixation, steroid eluting, pacing lead	1,248.00
	BT116	Siello S	Bipolar active fixation lead with fractal coated and steroid eluting electrode	1,248.00
	BT123	Safio S	Steroid eluting active fixation pacemaker lead with an electrically active extendable/ retractable screw for fixating the lead in the myocardium. The lead body is insulated in Silicone. The entire lead is conditionally safe to be used in a MRI system.	1,248.00
	BT139	TILDA R	Bipolar active fixation lead with fractal coated and steroid eluting electrode	1,248.00
Guidant Australia Pty Ltd	GU013	Fineline II EZ Sterox IROX Lead	Bipolar, active fixation	1,248.00
	GU016	Fineline II EZ Sterox IROX Lead	Bipolar, active fixation	1,248.00
	GU122	Flextend Lead Models 4086, 4087 & 4088	Bipolar, active fixation	1,248.00
Medtronic Australasia Pty Ltd	MC008	Medtronic Capsurefix Model 5568 Pacing Leads	Bipolar, steroid, active fixation pacing lead	1,215.00
	MC301	Model 3830 PACING LEADS	Active fixation pacemaker lead, Composition: Insulation is polyurethane, Electrodes are Titanium Nitride coated Platinum, the screw is steroid-coated	2,600.00
	MC338	Medtronic Capsurefix Novus Model 5076 Pacing Lead	Silicone; Contents: 1 x lead with anchoring sleeve, stylet & guide, 1 x vein lifter, 2 x fixation tools, extra stylets	1,248.00
	MC833	CapSureFix Novus Model 4076 Pacing Lead	Active fixation pacemaker lead	1,248.00
	MC936	CapSure Fix MRI Pacing Lead	Model 5086, MRI Conditional	1,248.00
Sorin Group Australia Pty Ltd	SA151	Physique ER Series	Steroid eluting active fixation pacing lead. Permanent pacing lead, Model Physique ER is indicated for the pacing and sensing of the ventricle or atrium. This permanent pacing lead is used in conjunction with a compatible implantable pulse generator. Permanent pacing lead, Model Physique ERJ is indicated for the pacing and sending of the atrium. This permanent pacing lead is used in conjunction with a compatible implantable pulse generator (pacemaker) IS-1	1,248.00

Sponsor	Billing code	Product name	Description	Min benefit ($)
	SA153	PY2-ER Series	Steroid eluting active fixation pacing lead. Permanent pacing lead PY2-ER series, is indicated for pacing and sensing of the ventricle and/or atrium of the heart. This lead is used in conjunction with a compatible implantable pulse generator (Pacemaker)	1,248.00
St Jude Medical Australia Pty Ltd	SJ073	Tendril SDX Models 1688TC	Endocardial Steroid-Eluting Active Fixation Pacing Lead	1,248.00
	SJ129	Tendril ST 1888TC and 1882TC	Endocardial Bi-polar Steroid-Eluting Active Fixation Pacing Leads	1,248.00
	SJ151	OptiSense Model 1999	Active-Fixation Bipolar, Steroid Eluting, endocardial, atrial pacing lead with Optim insulation	1,248.00
	SJ238	Tendril STS 2088TC	Endocardial Bi-polar Steroid-Eluting Additive Fixation Pacing Leads	1,248.00
	SJ270	Tendril MRI LPA 1200M	The Tendril MRI™ lead, Model LPA1200M, is an MR Conditional, bipolar, steroid-eluting, active fixation implantable pacing lead with Optim™ insulation.	1,248.00

Source: Prostheses List (February 2013) http://www.health.gov.au/internet/main/publishing.nsf/Content/prostheses-list-pdf.htm

APPENDIX 3: OVERVIEW OF SYSTEMATIC REVIEWS IDENTIFIED IN LITERATURE SEARCH

Meta-analysis	Studies included in analyses	N	Intervention	Comparator	Comparator	NYHA Class	Mean QRS Duration (ms)
Adabag (2011)	RAFT	1798	CRT+ICD	ICD	-	II-III	157
	MADIT-CRT	1820	CRT+ICD	ICD	-	I-II	65%>150
	REVERSE	610	CRT+ICD	ICD	-	I-II	154
	MIRACLE ICD II	186	CRT+ICD	ICD	-	II	165
	CONTAK CD†	581	CRT+ICD	ICD	-	II-IV	N/A
Al-Majed (2011)	RAFT	1798	CRT+ICD	ICD	-	II-III	157
	MADIT-CRT	1820	CRT+ICD	ICD	-	I-II	65%>150
	REVERSE	610	CRT+ICD	ICD	-	I-II	154
	MIRACLE ICD II	186	CRT+ICD	ICD	-	II	165
	Greater-EARTH‡	121	BIV First (+ICD)	LV First (+ICD)	-	I-III	153-157
	van Geldrop et al (2010)‡	37	CRT First	RV First	-	I-III	193-196
Bertoldi (2011)	MUSTIC SR, 2001‡	58	CRT on	CRT off	-	III	176
	MUSTIC A, 2002‡	43	CRT on	CRT off	-	III	209
	MIRACLE, 2002‡	453	CRT+MT	MT	-	III-IV	166
	CONTAK CD, 2003†	581	CRT+ICD	ICD	-	II-IV	N/A

Meta-analysis	Studies included in analyses	N	Intervention	Comparator	Comparator	NYHA Class	Mean QRS Duration (ms)
	MIRACLE ICD, 2003§	369	CRT+ICD	ICD	-	III-IV	164
	MIRACLE ICD II, 2004	186	CRT+ICD	ICD	-	II	165
	COMPANION, 2004	1520	CRT+ICD	ICD	MT	II-IV	160
	CARE HF, 2005‡	813	CRT+MT	MT	-	III-IV	160
	HOBIPACE, 2006‡	33	CRT	MY	-	I-IV	174
	REVERSE, 2008	610	CRT+ICD	ICD	-	I-II	154
	MADIT-CRT, 2009	1820	CRT+ICD	ICD	-	I-II	65%>150
	RAFT, 2010	1798	CRT+ICD	ICD	-	II-III	157
Chen (2012)	MIRACLE ICD, 2003§	369	CRT+ICD	ICD	-	III-IV	164
	CONTAK CD†	581	CRT+ICD	ICD	-	II-IV	N/A
	MIRACLE ICD II	186	CRT+ICD	ICD	-	II	165
	REVERSE, 2008	610	CRT+ICD	ICD	-	I-II	154
Lubitz (2010)	MADIT-CRT	1820	CRT+ICD	ICD	-	I-II	65%>150
	REVERSE	610	CRT+ICD	ICD	-	I-II	154
Santangeli (2011)	RAFT	1798	CRT+ICD	ICD	-	II-III	157
	MADIT-CRT	1820	CRT+ICD	ICD	-	I-II	65%>150
	REVERSE	610	CRT+ICD	ICD	-	I-II	154

Meta-analysis	Studies included in analyses	N	Intervention	Comparator	Comparator	NYHA Class	Mean QRS Duration (ms)
	MIRACLE ICD II	186	CRT+ICD	ICD	-	II	165
	CONTAK CD†	581	CRT+ICD	ICD	-	II-IV	N/A
Tu (2011)	RAFT	1798	CRT+ICD	ICD	-	II-III	157
	MADIT-CRT	1820	CRT+ICD	ICD	-	I-II	65%>150
	REVERSE	610	CRT+ICD	ICD	-	I-II	154
	MIRACLE ICD II	186	CRT+ICD	ICD	-	II	165
	CONTAK CD†	581	CRT+ICD	ICD	-	II-IV	N/A
	Greater-EARTH‡	121	BIV First (+ICD)	LV First (+ICD)	-	I-III	153-157
	van Geldrop et al (2010) ‡	37	CRT First	RV First	-	I-III	193-196
	CARE HF, 2005‡	813	CRT+MT	MT	-	III-IV	160
Wells (2011)	Lozano 2000†	222	CRT+ICD	ICD (cross over)	-	I-IV	NR
	MIRACLE ICD, 2003§	369	CRT+ICD	ICD	-	III-IV	164
	MIRACLE ICD II, 2004	186	CRT+ICD	ICD	-	II	165
	RHYTHM-ICD§	178	CRT+ICD	ICD	-	I-IV	168
	REVERSE, 2008	610	CRT+ICD	ICD	-	I-II	154
	MADIT-CRT, 2009	1820	CRT+ICD	ICD	-	I-II	65%>150
	RAFT, 2010	1798	CRT+ICD	ICD	-	II-III	157

Meta-analysis	Studies included in analyses	N	Intervention	Comparator	Comparator	NYHA Class	Mean QRS Duration (ms)
Zareba (2010)	REVERSE, 2008	610	CRT+ICD	ICD	-	I-II	154
	MADIT-CRT, 2009	1820	CRT+ICD	ICD	-	I-II	65%>150
	RAFT, 2010	1798	CRT+ICD	ICD	-	II-III	157

†Excluded due to wrong study type (cross over)
‡Excluded due to wrong intervention/comparator
§Excluded due to wrong patient population (NYHA not I-II or patient population with less than 10)
BIV, biventricular; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; LV, left ventricular; MT, medical therapy; NA, not available; NR, not reported; NYHA, New York Heart Association; RV, right ventricular

APPENDIX 4: LITERATURE SEARCH FOR UTILITY WEIGHT ESTIMATES

A comprehensive literature search was conducted to identify preference-based utility weights applicable to the proposed MBS population (see **Table C**). This search specifically aimed to identify publications that described preference-based utility weight estimates that were applicable to patients with chronic heart failure, were applicable to adverse outcomes (e.g. hospitalisation for heart failure), or were representative of differing levels of CRT-D or ICD treatment response.

Table C Literature search strategy

Database	Search terms	Citations retrieved	Final number of citations, excluding duplicates
EMBASE.com (includes Medline and EMBASE 1966 to present) (searched 9 April 2013)	#1 #theultimategenericutilitysearchv2 (#9)'cost utility analysis'/exp OR 'cost utility analysis' OR 'cost utility'/exp OR 'cost utility' OR 'standard gamble' OR 'time trade off' OR 'time tradeoff' OR 'qaly'/exp OR 'qaly' OR 'quality adjusted life years'/exp OR 'quality adjusted life years' OR 'preference weights' OR 'preference based health related quality of life' OR 'preference based hrqol' OR 'cost utilities' OR 'utility weight' OR 'utility weights' OR 'quality adjusted life year'/exp OR 'quality adjusted life year' OR 'utility value' OR 'utility values' OR 'multiattribute utility' OR (tto NOT 'tobacco retrotransposon' NOT ('tea tree oil'/exp OR 'tea tree oil')) OR 'health utilities' OR 'health utility' OR sf6d OR aqol OR 'australian quality of life' OR 'assessment of quality of life instrument' OR 'euroqol' OR eq5d OR 'short form 6d' OR 'hui 3' OR 'hui iii' OR (utility OR utilities AND ('quality of life'/exp OR 'quality of life'))	25,096	716
	#2 'heart failure'/exp	274,829	
Hand search		1	1
Number of citations retrieved by search			**717**
Number of citations excluded after title/abstract review:			
• Not a quality of life study			421
• Does not include patients with chronic heart failure			210
• Conference abstract			2
• Not in English			3
Total number of citations excluded after title/abstract review			636
Number of citations reviewed in full text			**81**
Number of citations excluded after full text review:			
• Wrong study type			16
• Does not include patients with chronic heart failure			1
• Does not report utility weights for a relevant health state			5
• Secondary publication			23
• Insufficient detail			4
Total number of included citations			**32**

In total, the literature search for relevant utility weight estimates identified 32 publications that reported preference-based utility weight estimates that related to chronic heart failure. The characteristics and results of these studies are presented in **Table D**.

Table D Summary of identified utility weight estimates

Study ID, country	Study description	Method of elicitation	Relevant health state	Utility
Alehagen 2008, Sweden	HRQoL study assessing utility weights among elderly patients with chronic heart failure (NYHA I-III)	TTO Elicited directly from patients in health state	NYHA class: I II III Self-assessed NYHA class: I II IIIa IIIb, IV	 0.75 (95% CI 0.72, 0.78) 0.71 (95% CI 0.66, 0.74) 0.56 (95% CI 0.49, 0.63) 0.77 (95% CI 0.74, 0.80) 0.68 (95% CI 0.65, 0.72) 0.61 (95% CI 0.55, 0.68) 0.50 (95% CI 0.38, 0.62)
Austin 2005, UK	RCT evaluating whether cardiac rehabilitation programmes can improve clinical outcomes in elderly patients with chronic heart failure (NYHA II/III)	EQ-5D Elicited directly from patients in health state	Mean utility of elderly patients with NYHA class II or III heart failure receiving outpatient clinic-based standard care at baseline	0.65
Austin 2008, UK	Long-term follow-up results of a RCT evaluating whether cardiac rehabilitation programmes can improve clinical outcomes in elderly patients with chronic heart failure (NYHA II/III)	EQ-5D Elicited directly from patients in health state	Mean utility of elderly patients with NYHA class II or III heart failure after five years of outpatient clinic-based standard care	0.60 (SD 0.34)
Capomolla 2002, Italy	Cohort study and CUA comparing a heart failure management program delivered in an outpatient hospital setting to standard care (NYHA I-IV)	TTO Elicited directly from patients in health state	Mean utility of heart failure patients after one year of standard care	0.63
Chen 2004, US	CUA of ICD for primary prevention of sudden cardiac death in patients with congestive heart failure	Assumptions based on literature	Patients with congestive heart failure at baseline Patients with congestive heart failure one year after ICD implantation Patients with congestive heart failure two years after ICD implantation	0.71 0.639 0.71
Cleland 2008, International	Long-term follow-up results of a RCT comparing CRT-P with OMT for the treatment of heart failure (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	Mean utility of patients with NYHA I or II heart failure at baseline	0.78 (95% CI 0.69, 0.85)

Study ID, country	Study description	Method of elicitation	Relevant health state	Utility
Cowie 2011, UK	CUA comparing highly purified omega-3 polyunsaturated fatty acid ethyl esters to standard care for the treatment of chronic heart failure (NYHA II-IV)	Estimated from the literature and expert opinion	Stable heart failure Decompensated heart failure leading to hospitalisation Stable post-decompensated heart failure MI Post-MI Stroke Post-stroke	0.67 (Range 0.51, 0.82) 0.50 (Range 0.43, 0.64) 0.67 (Range 0.51, 0.82) 0.62 (Range 0.47, 0.78) 0.67 (Range 0.51, 0.82) 0.58 (Range 0.39, 0.76) 0.62 (Range 0.47, 0.78)
De Rivas 2008, Spain	HRQoL study assessing utility weights among patients with chronic heart failure (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	Mean utility across all patients Mean utility of patients followed in primary care centres Mean utility of patients followed at cardiology outpatient clinics	0.63 (95% 0.62, 0.64) 0.60 (95% CI 0.59, 0.61) 0.68 (95% CI 0.66, 0.69)
Feldman 2005, International	RCT and CUA comparing CRT-D with CRT-P and OMT for the treatment of moderate to severe heart failure (NYHA III-IV)	Mapped from MLWHFQ scores elicited from patients in health state	Mean utility of patients with NYHA III or IV heart failure at baseline CRT-D: 3 months after CRT-D implant 6 months after CRT-D implant CRT-P: 3 months after CRT-P implant 6 months after CRT-P implant OPT 3 months 6 months	0.60-0.62 0.77 0.77 0.78 0.79 0.79 0.70
Feingold 2010, US	CUA of ICD implantation in children with dilated cardiomyopathy	Estimated from the literature	Disutility of system-related complications: ICD pocket infection ICD lead malfunction Inappropriate shock Generator change	 0.20 (Range 0, 0.6), applied for one month 0.12 (Range 0, 0.5), applied for one week 0.05 (Range 0, 0.5), applied for two days 0.1 (Range 0, 0.5), applied for half of one week
Ford 2012, Australia	CUA comparing hawthorne extract to standard care for the treatment of heart failure (NYHA I-IV)	Estimated from the literature	NYHA class I no hospitalisation NYHA class II no hospitalisation NYHA class III no hospitalisation	0.815 0.72 0.59

Study ID, country	Study description	Method of elicitation	Relevant health state	Utility
			NYHA class IV no	0.508 0.727)
			hospitalisation Disutility associated with hospitalisation	 -0.1 (assumption)
Gohler 2008, Germany	Decision-analytic evaluation of the cost-effectiveness of management programmes in chronic heart failure (NYHA class not reported)	EQ-5D Elicited directly from patients in health state	Index hospitalisation Rehospitalisation 1 Rehospitalisation 2 Rehospitalisation 3+	0.840 0.816 (disutility 0.024) 0.799 (disutility 0.041) 0.755 (disutility 0.085)
Gohler 2009, Germany	HRQoL substudy of RCT comparing administration of eplerenone to patients with heart failure after acute MI, versus standard care (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	*Utilities for a model based on NYHA class*	
			Intercept NYHA class: I II III IV	0.785 (SE 0.037) Reference -0.071 (SE 0.006) -0.161 (SE 0.009) -0.301 (SE 0.001)
			Utilities for a model based on the number of hospitalisations	
			Intercept First hospitalisation Rehospitalisation 1 Rehospitalisation 2 Rehospitalisation 3+	0.759 (SE 0.040) Reference -0.024 (SE 0.007) -0.031 (SE 0.009) -0.055 (SE 0.001)
Havranek 1999, US	HRQoL study assessing utility weights among a sample of 50 symptomatic patients with heart failure and a LVEF of <40% (NYHA class not reported)	TTO Elicited directly from patients in health state	Mean utility associated with heart failure	0.77 (SD 0.28)
Havranek 2004, US/Canada	HRQoL substudy of RCT comparing omapatrilat to eplerenone in patients with chronic heart failure (NYHA II-IV)	TTO Elicited directly from patients in health state	NYHA class: II III/IV	 0.82 (SD 0.25) 0.70 (SD 0.34)
Hebert 2008, US	CUA of a nurse-led disease management program for heart failure in an ethnically diverse urban community (NYHA I-IV)	HUI3 Elicited directly from patients in health state	Mean utility of patients with heart failure after one year of usual care	0.6122
Heidenreich 2004, US	CUA of a screening program to identify patients with low LVEF (NYHA not reported)	Estimated from the literature	Symptomatic heart failure Asymptomatic heart failure	0.71 0.87
Janssen 2011, Netherlands	HRQoL study assessing utility weights among a sample of patients with advanced COPD or heart failure (NYHA III/IV)	EQ-5D Elicited directly from patients in health state	Mean utility associated with NYHA III or IV heart failure	0.47 (SD 0.32)
Kontodimopoulos 2011, Greece	HRQoL study comparing EQ-5D and SF-6D utilities in a consecutive sample of patients undergoing elective cardiac surgery for	EQ-5D Elicited directly from patients in health state	Mean utility of patients undergoing elective surgery for chronic heart failure	0.703 (95% CI 0.665, 0.741)
		SF-6D	Mean utility of	0.710 (95% CI 0.693,

Study ID, country	Study description	Method of elicitation	Relevant health state	Utility
	treatment of chronic heart failure	Elicited directly from patients in health state	patients undergoing elective surgery for chronic heart failure	
Linde 2011, UK	CUA based on the REVERSE trial (NYHA I/II)	Estimated from the literature	NYHA class: I II III	 0.93 (95% CI 0.91, 0.96) 0.78 (95% CI 0.72, 0.84) 0.61 (95% CI 0.59, 0.63)
Miller 2009, US	CUA of the long-term impact of a systolic heart failure disease management programme (NYHA I-IV)	Estimated from SF-36	NYHA class: I II III or IV	 0.75 0.64 0.58
Moertl 2013, Austria and Canada	CUA of a NT-proBNP-guided, intensive patient management programme	Estimated from MLWHFQ	Utility of patients with heart failure with no additional hospitalisations	0.86 (SEM 0.01)
			Disutility per hospitalisation	0.02 (SEM 0.01)
Nichol 2004, US	CUA of CRT-P versus OMT in patients with patients with reduced ventricular function and prolonged QRS (NYHA II-IV)	SG Elicited directly from patients in health state	NYHA class III NYHA class IV Hospitalisation for heart failure	0.84 (Range 0.71, 0.98) 0.74 (Range 0.58, 0.91) 0.57 (Range 0.48, 0.80)
Noyes 2009, US	CUA of ICD versus OMT for patients with chronic heart failure (NYHA I-IV)	HUI3 Elicited directly from patients in health state	ICD: Baseline During follow-up OMT: Baseline During follow-up	 0.637 0.601 0.646 0.678
Noyes 2013 (MADIT-CRT), US	CUA based on the MADIT-CRT trial (NYHA I/II)	EQ-5D Elicited directly from patients in health state	CRT-D: Baseline During follow-up ICD: Baseline During follow-up	 0.848 (SD 0.134) 0.884 (SD 0.145) 0.845 (SD 0.134) 0.874 (SD 0.145)
Ozasa 2008, Japan	CUA of ICD implantation in patients with chronic heart failure	TTO Questionnaire administered to 27 cardiologists	ICD, with well condition ICD with any complication Conventional management with well condition Conventional management with any complication	0.792 (Range 0.670, 0.915) 0.589 (Range 0.447, 0.731) 0.833 (Range 0.737, 0.929) 0.604 (Range 0.458, 0.749)
Patel 2008, Sweden	Pilot study and CUA of home care as an option for the management of worsening chronic heart failure (NYHA II-IV)	EQ-5D Elicited directly from patients in health state SG Elicited directly from patients in health state	Mean utility of heart failure patients after one year of conventional care Mean utility of heart failure patients after one year of conventional care	0.43 0.64
Pradelli 2009,	CUA of valsartan for the	Estimated from	NYHA class:	

Study ID, country	Study description	Method of elicitation	Relevant health state	Utility
Italy	treatment of chronic heart failure (NYHA II-IV)	the literature	II III IV	0.813 0.750 0.680
			Disutility of hospitalisation	-0.10
Pressler 2011, US	HRQoL study in 211 patients with chronic heart failure (NYHA I-IV)	HUI3 Elicited directly from patients in health state	Mean utility of patients with chronic heart failure	0.49 (SD 0.34)
Riberio 2010, Brazil	CUA of ICD implantation in patients with chronic heart failure (NYHA II or III)	Estimated from the literature	Utility of a patient with chronic heart failure Utility of a patient with chronic heart failure and an ICD	0.88 (Range 0.71, 0.88) 0.88 (Range 0.64, 0.88)
Sanders 2010, US	CUA of ICD implantation in patients aged 65 years or more with chronic heart failure	Estimated from the literature	Baseline health state (conventional therapy)	0.88 (Range 0.6, 1.0)
			After ICD implantation	0.88 (Range 0.6, 1.0)
Yao 2007, UK	Trial-based CUA comparing CRT-D with CRT-P (NYHA I-IV)	EQ-5D Elicited directly from patients in health state	NYHA class: I II III IV	 0.815 (95% CI 0.781, 0.850) 0.720 (95% CI 0.720, 0.693) 0.590 (95% CI 0.590, 0.551) 0.508 (95% CI 0.508, 0.412)

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; CRT-D, cardiac resynchronisation therapy device capable of defibrillation; CRT-P, cardiac resynchronisation therapy pacemaker; CUA, cost-utility analysis; EQ-5D, EuroQol-5 Dimensions; HRQoL, health-related quality of life; HUI3, health utilities index mark 3; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MLWHF, Minnesota Living with Heart Failure Questionnaire; NT-proBNP, N-terminal prohormone of brain natriuretic peptide; NYHA, New York Heart Association; OMT, optimised medical therapy; RCT, randomised controlled trial; SD, standard deviation; SEM, standard error of the mean; SF-36, Short Form 36 Health Survey; SF-6D, Short Form 6 dimensions; SG, standard gamble; TTO, time-trade-off

APPENDIX 5: LITERATURE SEARCH OUTPUT

LITERATURE SEARCH FOR DIRECT COMPARATIVE RANDOMISED TRIALS

Original search date: 19 September 2013

Abdulla J, Haarbo J, Kober L, and Torp-Pedersen C. (2006) Impact of implantable defibrillators and resynchronization therapy on outcome in patients with left ventricular dysfunction - A meta-analysis. Cardiology 106:249-255. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Abdulla J, Haarbo J, Kober L, and Torp PC. (2006) Impact of implantable defibrillators and resynchronization therapy on outcome in patients with left ventricular dysfunction: a meta-analysis (Structured abstract). Cardiology 106:249-255. Notes: Duplicate.

Abou Ezzeddine OF, Mirzoyev SA, and Redfield MM. (2009) The conundrum of appropriate ICD utilization in heart failure patients: Impact of age, comorbidities and potential for improved ejection fraction with therapy. Journal of Cardiac Failure 15:S90. Notes: Title/abstract: Excluded. Wrong study type.

Abraham JE, Thomas J, and Wilkoff B. (2011) Cardiac resynchronization therapy for exercise-induced left ventricular dysfunction. Heart Rhythm 8:S49. Notes: Title/abstract: Excluded. Wrong study type.

Abraham WT. (2003) Cardiac resynchronization therapy: A review of clinical trials and criteria for identifying the appropriate patient. Reviews in Cardiovascular Medicine 4:S30-S37. Notes: Title/abstract: Excluded. Wrong study type.

Abraham WT, Young JB, Leon AR, Adler S, Bank AJ, Hall SA, Lieberman R, Liem LB, O'Connell JB, Schroeder JS, and Wheelan KR. (2004) Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. Circulation 110:2864-2868. Notes: Title/abstract: Included. Full text: Included. MIRACLE ICD II.

Abraham WT, Young JB, León AR, Adler S, Bank AJ, Hall SA, Lieberman R, Liem LB, O'Connell JB, Schroeder JS, and Wheelan KR. (2004) Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. Circulation 110:2864-2868. Notes: Duplicate.

Abraham WT, Compton S, Haas G, Foreman B, Canby RC, Fishel R, Mcrae S, Toledo GB, Sarkar S, and Hettrick DA. (2011) Intrathoracic Impedance vs Daily Weight Monitoring for Predicting Worsening Heart Failure Events: Results of the Fluid Accumulation Status Trial (FAST). Congestive Heart Failure 17:51-55. Notes: Title/abstract: Excluded. Wrong study type.

Abraham WT, Leon AR, John Sutton MG, Keteyian SJ, Fieberg AM, Chinchoy E, and Haas G. (2012) Randomized controlled trial comparing simultaneous versus optimized sequential interventricular stimulation during cardiac resynchronization therapy. American heart journal 164:735-741. Notes: Title/abstract: Excluded. Wrong indication.

Achilli A, Sassara M, Pontillo D, Turreni F, Scrimieri P, Achilli P, and Poggiaroni A. (2006) In the light of trials data on CRT, should the defibrillator be always associated with a biventricular stimulator? Mediterranean Journal of Pacing and Electrophysiology 8:1-6. Notes: Title/abstract: Excluded. Wrong study type.

Achtelik M, Bocchiardo M, Trappe HJ, Gaita F, Lozano I, Niazi I, Gold M, Yong P, and Duby C. (2000) Performance of a new steroid-eluting coronary sinus lead designed for left ventricular pacing. PACE -

Pacing and Clinical Electrophysiology 23:1741-1743. Notes: Title/abstract: Excluded. Wrong intervention.

Achtelik M, Bocchiardo M, Trappe HJ, Gaita F, Lozano I, Niazi I, Gold M, Yong P, and Duby C. (2000) Performance of a new steroid-eluting coronary sinus lead designed for left ventricular pacing. Pacing and clinical. electrophysiology. : PACE 23:1741-1743. Notes: Duplicate.

Acosta A, Riley JP, and Cowie MR. (2011) Integrating remote monitoring to heart failure management. European Journal of Heart Failure, Supplement 10:S55. Notes: Title/abstract: Excluded. Wrong study type.

Adabag S, Roukoz H, Anand IS, and Moss AJ. (2011) Cardiac resynchronization therapy in patients with minimal heart failure: A systematic review and meta-analysis. Journal of the American College of Cardiology 58:935-941. Notes: Title/abstract: Included. Full text: Included. SR

Adabag S, Roukoz H, Anand IS, and Moss AJ. (2011) Cardiac resynchronization therapy in patients with minimal heart failure: a systematic review and meta-analysis (Structured abstract). Journal of the. American. College. of Cardiology 58:935-941. Notes: Duplicate.

Adamson PB, Kleckner KJ, VanHout WL, Srinivasan S, and Abraham WT. (2003) Cardiac resynchronization therapy improves heart rate variability in patients with symptomatic heart failure. Circulation 108:266-269. Notes: Title/abstract: Excluded. Wrong intervention.

Adelstein EC, Shalaby A, and Saba S. (2010) Cardiac resynchronization differentially impacts survival in heart failure patients based upon baseline renal function. Journal of the American College of Cardiology 55:A30. Notes: Title/abstract: Excluded. Wrong study type.

Adelstein EC, Bhattacharya S, and Saba S. (2010) Predicting survival among patients undergoing cardiac resynchronization using a simple scoring system. Journal of the American College of Cardiology 55:A24. Notes: Title/abstract: Excluded. Wrong study type.

Adelstein EC, Bhattacharya S, Simon M, Gorcsan J, and Saba S. (2011) Non-ischemic cardiomyopathy patients receiving intravenous inotropes have poor outcomes despite cardiac resynchronization therapy. Heart Rhythm 8:S63-S64. Notes: Title/abstract: Excluded. Wrong study type.

Adelstein EC, Schwartzman D, and Saba S. (2011) Atrial fibrillation does not impact survival after cardiac resynchronization despite diminished echocardiographic improvement. Journal of the American College of Cardiology 57:E160. Notes: Title/abstract: Excluded. Wrong study type.

Afolabi BA and Kusumoto FM. (2012) Remote monitoring of patients with implanted cardiac devices-A review. European Cardiology 8:88-93. Notes: Title/abstract: Excluded. Wrong study type.

Aidelsburger P, Grabein K, Klauss V, and Wasem J. (2008) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator (CRT-D) for the treatment of chronic heart failure from a German health care systemperspective. Clinical Research in Cardiology 97:89-97. Notes: Title/abstract: Excluded. Wrong study type.

Al-Khatib SM, Sanders GD, Mark DB, Lee KL, Bardy GH, Bigger JT, Buxton AE, Connolly S, Kadish A, Moss A, Feldman AM, Ellenbogen KA, Singh S, and Califf RM. (2005) Implantable cardioverter defibrillators and cardiac resynchronization therapy in patients with left ventricular dysfunction: Randomized trial evidence through 2004. American heart journal 149:1020-1034. Notes: Title/abstract: Excluded. Wrong study type.

Al-Majed NS, McAlister FA, Bakal JA, and Ezekowitz JA. (2011) Meta-analysis: cardiac resynchronization therapy for patients with less symptomatic heart failure (Structured abstract). Annals. of Internal. Medicine 154:401-412. Notes: Title/abstract: Included. Full text: Included. SR

Albert NM, Fonarow GC, Yancy CW, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride M, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2010) Influence of dedicated heart failure

clinics on delivery of recommended therapies in outpatient cardiology practices: Findings from the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF). American heart journal 159:238-244. Notes: Title/abstract: Excluded. Wrong study type.

Albert NM, Fonarow GC, Yancy CW, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride M, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2010) Outpatient Cardiology Practices With Advanced Practice Nurses and Physician Assistants Provide Similar Delivery of Recommended Therapies (Findings from IMPROVE HF). American Journal of Cardiology 105:1773-1779. Notes: Title/abstract: Excluded. Wrong study type.

Albert NM, O'Malley M, Nutter B, and Starling R. (2011) Do advanced practice nurses conform to heart failure therapies at the same rate as team-based physicians? Journal of Cardiac Failure 17:S99. Notes: Title/abstract: Excluded. Wrong study type.

Almajed N, McAlister FA, and Ezekowitz J. (2010) Cardiac resynchronization therapy in patients with heart failure; A systematic review and meta-analysis of randomized controlled trials. Canadian Journal of Cardiology 26:92D. Notes: Title/abstract: Excluded. Wrong study type.

Altin T, Akyurek O, Vurgun K, Beton O, Sayin T, Kilickap M, Karaoguz R, Guldal M, and Erol C. (2007) Effect of transvenous cardiac resynchronization therapy device implantation on cardiac troponin I release. Pacing and clinical. electrophysiology. : PACE 30:1356-1362. Notes: Title/abstract: Excluded. Wrong study type.

Ammann P, Kiencke S, Schaer B, Cron TA, Sticherling C, Huldi C, Linka A, Buser P, Pfisterer M, and Osswald S. (2004) Cardiac resynchronization in severe heart failure and left bundle branch block: A single centre experience. Swiss Medical Weekly 134:277-282. Notes: Title/abstract: Excluded. Wrong study type.

Ammirati E, Guida V, Rimoldi OE, and Camici PG. (2012) Revascularization of hibernating myocardium: A clinical problem still unresolved. Giornale Italiano di Cardiologia 13:102-109. Notes: Title/abstract: Excluded. Wrong study type.

Anand IS, Carson P, Galle E, Song R, Boehmer J, Ghali JK, Jaski B, Lindenfeld J, O'Connor C, Steinberg JS, Leigh J, Yong P, Kosorok MR, Feldman AM, DeMets D, and Bristow MR. (2009) Cardiac resynchronization therapy reduces the risk of hospitalizations in patients with advanced heart failure results from the comparison of medical therapy, pacing and defibrillation in heart failure (COMPANION) trial. Circulation 119:969-977. Notes: Title/abstract: Excluded. Wrong indication.

Anand IS, Carson P, Galle E, Song R, Boehmer J, Ghali JK, Jaski B, Lindenfeld J, O'Connor C, Steinberg JS, Leigh J, Yong P, Kosorok MR, Feldman AM, DeMets D, and Bristow MR. (2009) Cardiac resynchronization therapy reduces the risk of hospitalizations in patients with advanced heart failure: results from the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) trial. Circulation 119:969-977. Notes: Duplicate.

Andrikopoulos G, Tzeis S, Theodorakis G, and Vardas P. (2010) Monitoring capabilities of cardiac rhythm management devices. Europace 12:17-23. Notes: Title/abstract: Excluded. Wrong study type.

Andriulli JA, Heywood JT, Small R, Tang W, Hettrick D, and Miller CT. (2011) ICD and CRT-D heart failure patients with an intrathoracic impedance fluid index threshold crossing have significantly increased risk of ventricular tachyarrhythmias. Journal of Cardiac Failure 17:S51. Notes: Title/abstract: Excluded. Wrong study type.

Anguita M, Comin-Colet J, Formiga F, Almenar L, Leiro M, Manzano L, Chaves J, and De Frutos T. (2012) Does age influences treatment of patients with heart failure and depressed systolic function? Results of a real world study (VIDA-IC study). European Heart Journal 33:162. Notes: Title/abstract: Excluded. Wrong study type.

Anh D, Srivatsa U, Bui HM, Vasconcellos S, and Narayan SM. (2008) Biventricular pacing attenuates T-wave alternans and T-wave amplitude compared to other pacing modes. PACE - Pacing and Clinical Electrophysiology 31:714-721. Notes: Title/abstract: Excluded. Wrong study type.

Ansalone G, Boriani G, Kranig W, Donal E, Calo L, Casella M, Delarche N, Lozano I, Boulogne E, and Leclercq C. (2009) Biventricular or left ventricular only pacing for cardiac resynchronization therapy: Echocardiographic results of the double-blind randomized B-LEFT HF study. European Heart Journal 30:871. Notes: Title/abstract: Excluded. Wrong study type.

Ansalone G, Bortani G, Kranig W, Donal E, Calo L, Casella M, Delarche N, Lozano I, Boulogne E, and Leclercq C. (2010) BiV or LV only pacing for CRT: Echocardiographic results of the B-LEFT study. Europace 12:i49. Notes: Title/abstract: Excluded. Wrong study type.

Antz M and Bansch D. (2005) Idiopathic dilated cardiomyopathy-an appraisal in 2005. Herz 30:87-90. Notes: Title/abstract: Excluded. Wrong study type.

Arbeo E, Quintana AG, Diaz M, Caballero E, Moreno B, Rios C, Ramirez R, and Medina A. (2009) Relationship between clinical response and cardiac remodeling in patients treated with cardiac resynchronization therapy. Journal of Cardiovascular Electrophysiology 20:S39-S40. Notes: Title/abstract: Excluded. Wrong study type.

Arias MA, Pachon M, Puchol A, Jimenez-Lopez J, and Rodriguez-Padial L. (2012) Acute and mid-term outcomes of transvenous implant of a new left ventricular quadripolar lead versus bipolar leads for cardiac resynchronization therapy: Results from a single-center prospective database. Cardiology Journal 19:470-478. Notes: Title/abstract: Excluded. Wrong study type.

Arnold JM, Newton G, Mielniczuk L, Talajic M, Yee R, Wells GA, and Tang A. (2011) Cardiac resynchronization therapy is an effective therapy for patients with impaired renal function. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Aronow WS. (2005) CRT plus ICD in congestive heart failure: Use of cardiac resynchronization therapy and an implantable cardioverter-defibrillator in heart failure patients with abnormal left ventricular dysfunction. Geriatrics 60:24-28. Notes: Title/abstract: Excluded. Wrong study type.

Aronow WS. (2006) Treatment of heart failure with decreased left ventricular ejection fraction. Comprehensive Therapy 32:218-225. Notes: Title/abstract: Excluded. Wrong study type.

Aronow WS. (2009) Treatment of ventricular arrhythmias in the elderly. Cardiology in Review 17:136-146. Notes: Title/abstract: Excluded. Wrong study type.

Aronow WS. (2010) Use of implantable cardioverter-defibrillators. Future Cardiology 6:859-870. Notes: Title/abstract: Excluded. Wrong study type.

Aronow WS. (2010) Management of ventricular arrhythmias. Minerva Cardioangiologica 58:657-676. Notes: Title/abstract: Excluded. Wrong study type.

Arshad A, Moss AJ, Foster E, Padeletti L, Barsheshet A, Goldenberg I, Greenberg H, Hall WJ, McNitt S, Zareba W, Solomon S, and Steinberg JS. (2011) Cardiac resynchronization therapy is more effective in women than in men: The MADIT-CRT (multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy) trial. Journal of the American College of Cardiology 57:813-820. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Arslan Z, Tanabe K, Bhamre S, Polonsky S, Moss AJ, Mc Nitt S, Zareba W, Wang PJ, and Al-Ahmad A. (2012) Percent pacing in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) study. Heart Rhythm 9:S374. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Arujuna AV, Ginks M, and Rinaldi A. (2008) Future of cardiac resynchronization therapy. Future Cardiology 4:191-201. Notes: Title/abstract: Excluded. Wrong study type.

Asbach S, Hartmann M, Wengenmayer T, Hilgendorf I, Faber T, Bode C, and Biermann J. (2012) The stimulation site of quadripolar left ventricular pacing affects hemodynamics. Heart Rhythm 9:S374. Notes: Title/abstract: Excluded. Wrong study type.

Asghar H and Rahko PS. (2010) Quality of heart failure management: A comparison of care between a comprehensive heart failure program and a general cardiology practice. Congestive Heart Failure 16:65-70. Notes: Title/abstract: Excluded. Wrong study type.

Auer J. (2009) Management of chronic heart failure. Journal fur Kardiologie 16:429-439. Notes: Title/abstract: Excluded. Wrong study type.

Augello G, Santinelli V, Vicedomini G, Mazzone P, Gulletta S, Maggi F, Mika Y, Chierchia G, and Pappone C. (2004) Cardiac contractility modulation by non-excitatory electrical currents. The new frontier for electrical therapy of heart failure. Italian heart journal : official journal of the Italian Federation of Cardiology 5 Suppl 6:68S-75S. Notes: Title/abstract: Excluded. Wrong study type.

Augostini R, Pelini M, Zhang S, Stoycos S, Witsaman S, Mowrey K, Bremer J, and Oza A. (2011) OptiSense lead in detecting atrial fibrillation: results from the SENSE-AF study. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Spinnelli JC. (2003) The promise of resynchronization therapy. Who (and how many) will benefit? Cardiac electrophysiology review 7:17-26. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Fantoni C. (2004) Cardiac resynchronization therapy in heart failure: Which type and for whom? Dialogues in Cardiovascular Medicine 9:225-231. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Abraham WT. (2004) Cardiac Resynchronization Therapy: Current State of the Art. Cost Versus Benefit. Circulation 109:300-307. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Fantoni C. (2005) Cardiac resynchronization therapy in heart failure. Italian Heart Journal 6:256-260. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A, Metra M, Gasparini M, Lamp B, Klersy C, Curnis A, Fantoni C, Gronda E, and Vogt J. (2007) Long-Term Survival of Patients With Heart Failure and Ventricular Conduction Delay Treated With Cardiac Resynchronization Therapy. American Journal of Cardiology 99:232-238. Notes: Duplicate.

Auricchio A, Metra M, Gasparini M, Lamp B, Klersy C, Curnis A, Fantoni C, Gronda E, and Vogt J. (2007) Long-term survival of patients with heart failure and ventricular conduction delay treated with cardiac resynchronization therapy. The. American. journal of cardiology 99:232-238. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Moccetti T. (2010) Electronic cardiac medicine: Present and future opportunities. Swiss Medical Weekly 140. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A, Schillinger W, Meyer S, Maisano F, Hoffmann R, Ussia GP, Pedrazzini GB, Van Der Heyden J, Fratini S, and Franzen O. (2011) Correction of mitral regurgitation by mitraclip in non-responders to cardiac resynchronization therapy improves symptoms and promotes reverse remodeling. European Heart Journal 32:499. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A, Meijer A, Kurita T, Schloss E, Brinkman K, Claessens-Van Ooijen M, and Sterns L. (2011) Safety, efficacy, and performance of new discrimination algorithms to reduce inappropriate and unnecessary shocks: The PainFree SST clinical study design. Europace 13:1484-1493. Notes: Title/abstract: Excluded. Wrong study type.

Babu GG, Kumar S, Gopalamurugan A, Lambiase P, Chow A, and Segal O. (2010) Chronic kidney disease is an independent predictor of sustained ventricular arrhythmia in heart failure patients with

primary prevention CRT-D devices. Journal of Interventional Cardiac Electrophysiology 27:180-181. Notes: Title/abstract: Excluded. Wrong study type.

Babu GG, Kumar S, Gopalamurugan AB, Lambiase P, Chow A, and Segal O. (2010) Chronic kidney disease is an independent predictor of sustained ventricular arrhythmia in heart failure patients with primary prevention cardiac resynchronization therapy devices. Heart Rhythm 7:S57. Notes: Title/abstract: Excluded. Wrong study type.

Bai R, Biase LD, Elayi C, Ching CK, Barrett C, Philipps K, Lim P, Patel D, Callahan T, Martin DO, Arruda M, Schweikert RA, Saliba WI, Wilkoff B, and Natale A. (2008) Mortality of heart failure patients after cardiac resynchronization therapy: Identification of predictors. Journal of Cardiovascular Electrophysiology 19:1259-1265. Notes: Title/abstract: Excluded. Wrong study type.

Bai R, Biase L, Elayi C, Ching CK, Barrett C, Philipps K, Lim P, Patel D, Callahan T, Martin DO, Arruda M, Schweikert RA, Saliba WI, Wilkoff B, and Natale A. (2008) Mortality of heart failure patients after cardiac resynchronization therapy: identification of predictors. Journal of cardiovascular. electrophysiology. 19:1259-1265. Notes: Duplicate.

Baker II JH, McKenzie III J, Beau S, Greer GS, Porterfield J, Fedor M, Greenberg S, Daoud EG, Corbisiero R, Bailey JR, and Porterfield L. (2007) Acute evaluation of programmer-guided AV/PV and VV delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. Journal of Cardiovascular Electrophysiology 18:185-191. Notes: Title/abstract: Excluded. Wrong study type.

Bank AJ, Burns KV, Gage RM, Vatterott DB, Adler SW, Sajady M, Rohde D, Parah JS, Anand I, Yong P, Seth M, and Kubo SH. (2012) Cardiac resynchronization therapy in the real world: Comparison with the COMPANION study. Journal of Cardiac Failure 18:153-158. Notes: Title/abstract: Excluded. Wrong study type.

Baptista R, Jorge E, Saraiva F, Martins H, Mendes P, Lourenco C, Costa S, Monteiro P, Franco F, and Providencia LA. (2010) The value of Implantable Cardioverter Defibrillator in an unselected advanced heart failure clinic: A safe and very efficient therapy. European Journal of Heart Failure, Supplement 9:S140. Notes: Title/abstract: Excluded. Wrong study type.

Baravelli M, Albini A, Rossi A, Cattaneo P, and Anza C. (2011) Cardiac resynchronization therapy for treatment of trastuzumab-related cardiomyopathy. Giornale Italiano di Cardiologia 12:161S. Notes: Title/abstract: Excluded. Wrong study type.

Barbhaiya C, Po JRF, Hanon S, and Schweitzer P. (2013) Tpeak-Tend and Tpeak-Tend/QT ratio as markers of ventricular arrhythmia risk in cardiac resynchronization therapy patients. PACE - Pacing and Clinical Electrophysiology 36:103-108. Notes: Title/abstract: Excluded. Wrong study type.

Barnett D, Phillips S, and Longson C. (2007) Cardiac resynchronisation therapy for the treatment of heart failure: NICE technology appraisal guidance. Heart 93:1134-1135. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Barold SS. (2001) What is cardiac resynchronization therapy? American Journal of Medicine 111:224-232. Notes: Title/abstract: Excluded. Wrong study type.

Barsheshet A, Wang PJ, Moss AJ, Solomon SD, Al-Ahmad A, McNitt S, Foster E, Huang DT, Klein HU, Zareba W, Eldar M, and Goldenberg I. (2011) Reverse remodeling and the risk of ventricular tachyarrhythmias in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation TrialCardiac Resynchronization Therapy). Journal of the American College of Cardiology 57:2416-2423. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Barsheshet A, Goldenberg I, Moss AJ, Eldar M, Huang DT, McNitt S, Klein HU, Hall WJ, Brown MW, Goldberger JJ, Goldstein RE, Schuger C, Zareba W, and Daubert JP. (2011) Response to preventive cardiac resynchronization therapy in patients with ischaemic and nonischaemic cardiomyopathy in

MADIT-CRT. European Heart Journal 32:1622-1630. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Barsheshet A, Wang PJ, Moss AJ, Solomon SD, Al AA, McNitt S, Foster E, Huang DT, Klein HU, Zareba W, Eldar M, and Goldenberg I. (2011) Reverse remodeling and the risk of ventricular tachyarrhythmias in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy). Journal of the. American. College. of Cardiology 57:2416-2423. Notes: Duplicate

Barsheshet A, Goldenberg I, Moss AJ, Eldar M, Huang DT, McNitt S, Klein HU, Hall WJ, Brown MW, Goldberger JJ, Goldstein RE, Schuger C, Zareba W, and Daubert JP. (2011) Response to preventive cardiac resynchronization therapy in patients with ischaemic and nonischaemic cardiomyopathy in MADIT-CRT. European. Heart Journal 32:1622-1630. Notes: Duplicate

Barsheshet A, Moss AJ, Eldar M, Huang DT, Hall WJ, Klein HU, McNitt S, Steinberg JS, Wilber DJ, Zareba W, and Goldenberg I. (2011) Time-dependent benefit of preventive cardiac resynchronization therapy after myocardial infarction. European. Heart Journal 32:1614-1621. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Barsheshet A, Moss AJ, McNitt S, Jons C, Glikson M, Klein HU, Huang DT, Steinberg JS, Brown MW, Zareba W, and Goldenberg I. (2011) Long-term implications of cumulative right ventricular pacing among patients with an implantable cardioverter-defibrillator. Heart rhythm. : the. official. journal of the. Heart Rhythm. Society. 8:212-218. Notes: Title/abstract: Excluded. Wrong indication.

Barsheshet A, Brenyo A, Goldenberg I, and Moss AJ. (2012) Sex-related differences in patients' responses to heart failure therapy. Nature Reviews Cardiology 9:234-242. Notes: Title/abstract: Excluded. Wrong study type.

Bauer A, Zurn CS, and Schmidt G. (2010) Heart rate turbulence to guide treatment for prevention of sudden death. Journal of Cardiovascular Pharmacology 55:531-538. Notes: Title/abstract: Excluded. Wrong study type.

Bauer A, Bode F, Le Gal F, Deharo JC, Delay M, Nitzsche R, and Clementy J. (2011) Clinical predictors of VT/VF events in a CRT-D population. Europace 13. Notes: Title/abstract: Excluded. Wrong intervention.

Beau SL, Corbisiero R, and David Thompson W. (2010) Safety and efficacy of novel algorithms to determine capture and adjust outputs in ICD/CRT-D devices. Europace 12:i96. Notes: Title/abstract: Excluded. Wrong study type.

Becker M, Erdmann N, Stegemann E, Benke D, Schauerte PN, Schaefer WM, Autschbach R, Kelm M, and Koch KC. (2008) Survival and Quality of Life in Patients With Cardiac Resynchronization Therapy for Severe Heart Failure and in Heart Transplant Recipients Within a Contemporary Heart Failure Management Program. Journal of Heart and Lung Transplantation 27:746-752. Notes: Title/abstract: Excluded. Wrong study type.

Behan MWH and Rinaldi CA. (2006) Cardiac resynchronisation therapy for heart failure. International Journal of Clinical Practice 60:1107-1114. Notes: Title/abstract: Excluded. Wrong study type.

Belardinelli R, Capestro F, Misiani A, Scipione P, and Georgiou D. (2006) Moderate exercise training improves functional capacity, quality of life, and endothelium-dependent vasodilation in chronic heart failure patients with implantable cardioverter defibrillators and cardiac resynchronization therapy. European Journal of Cardiovascular Prevention and Rehabilitation 13:818-825. Notes: Title/abstract: Excluded. Wrong study type.

Belardinelli R, Capestro F, Misiani A, Scipione P, and Georgiou D. (2006) Moderate exercise training improves functional capacity, quality of life, and endothelium-dependent vasodilation in chronic heart failure patients with implantable cardioverter defibrillators and cardiac resynchronization

therapy. European. journal of cardiovascular. prevention. and rehabilitation : official. journal of the. European. Society. of Cardiology, Working. Groups. on Epidemiology & Prevention. and Cardiac. Rehabilitation and Exercise. Physiology. 13:818-825. Notes: Duplicate.

Bentkover JD, Dorian P, Thibault B, and Gardner M. (2007) Economic analysis of a randomized trial of biventricular pacing in Canada. PACE - Pacing and Clinical Electrophysiology 30:38-43. Notes: Title/abstract: Excluded. Wrong study type.

Berberian G, Cabreriza SE, Quinn TA, Garofalo CA, and Spotnitz HM. (2006) Left Ventricular Pacing Site-Timing Optimization During Biventricular Pacing Using a Multi-Electrode Patch. Annals of Thoracic Surgery 82:2292-2294. Notes: Title/abstract: Excluded. Wrong study type.

Berger M, Toluie K, Barnett C, Mathews S, and Harbert N. (2010) Clinical characteristics of patients receiving CRT devices: Do gender differences exist? Heart Rhythm 7:S73. Notes: Title/abstract: Excluded. Wrong study type.

Berger RD. (2005) ICD update: New evidence and emerging clinical roles in primary prevention of sudden cardiac death. Advanced Studies in Medicine 5:468-474. Notes: Title/abstract: Excluded. Wrong study type.

Bernard ML and Gold MR. (2011) Economic Implications and Cost-effectiveness of Implantable Cardioverter Defibrillator and Cardiac Resynchronization Therapy. Heart Failure Clinics 7:241-250. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Polanczyk CA, Cunha V, Ziegelmann PK, Beck-Da-Silva L, and Rohde LE. (2011) Mortality reduction of cardiac resynchronization and implantable cardioverter-defibrillator therapy in heart failure: An updated meta-analysis. does recent evidence change the standard of care? Journal of Cardiac Failure 17:860-866. Notes: Title/abstract: Included. Full text: Included. SR

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. International Journal of Cardiology. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Polanczyk CA, Cunha V, Ziegelmann PK, Beck-da SL, and Rohde LE. (2011) Mortality reduction of cardiac resynchronization and implantable cardioverter-defibrillator therapy in heart failure: an updated meta-analysis. Does recent evidence change the standard of care? (Provisional abstract). Journal of Cardiac. Failure. 17:860-866. Notes: Duplicate.

Berul CI, Freedenberg V, Atallah J, Balaji S, Bar-Cohen Y, Batra AS, Cannon BC, Ceresnak S, Chun TU, Cohen MI, Collins KK, Dubin AM, Erickson C, Franklin WH, Kertesz NJ, LaPage MJ, Law IH, Moak JP, Papagiannis J, Paul T, Tanel RE, Tisma-Dupanovic S, Wilkoff BL, Zimmerman F, and Cecchin F. (2011) Results of the pediatric lead extractability and survival evaluation (Please) study. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type.

Beshai JF, Grimm RA, Nagueh SF, Baker II JH, Beau SL, Greenberg SM, Pires LA, and Tchou PJ. (2007) Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. New England Journal of Medicine 357:2461-2471. Notes: Title/abstract: Excluded. Wrong indication.

Beshai JF and Grimm R. (2007) The resynchronization therapy in narrow QRS study (RethinQ study): Methods and protocol design. Journal of Interventional Cardiac Electrophysiology 19:149-155. Notes: Title/abstract: Excluded. Wrong indication

Beshai JF, Grimm RA, Nagueh SF, Baker JH, Beau SL, Greenberg SM, Pires LA, and Tchou PJ. (2007) Cardiac-resynchronization therapy in heart failure with narrow QRS complexes. The. New England. journal of medicine 357:2461-2471. Notes: Duplicate.

Beshai JF and Grimm R. (2007) The resynchronization therapy in narrow QRS study (RethinQ study): methods and protocol design. Journal of interventional. cardiac. electrophysiology. : an. international. journal of arrhythmias. and pacing 19:149-155. Notes: Duplicate.

Bevilacqua LM and Berul CI. (2004) Advances in pediatric electrophysiology. Current Opinion in Pediatrics 16:494-499. Notes: Title/abstract: Excluded. Wrong study type.

Bhatia A, Cooley R, Berger M, Blanck Z, Dhala A, Sra J, Axtell-McBride K, VanderVort C, and Akhtar M. (2004) The implantable cardioverter defibrillator: Technology, indications, and impact on cardiovascular survival. Current Problems in Cardiology 29:303-356. Notes: Title/abstract: Excluded. Wrong study type.

Bhatia V, Bhatia R, Dhindsa S, and Virk A. (2003) Cardiac resynchronization therapy in heart failure: Recent advances and new insights. Indian Pacing and Electrophysiology Journal 3:129-142. Notes: Title/abstract: Excluded. Wrong study type.

Biffi M, Ziacchi M, Bertini M, Sangiorgi D, Corsini D, Martignani C, Diemberger I, and Boriani G. (2008) Longevity of implantable cardioverter-defibrillators: Implications for clinical practice and health care systems. Europace 10:1288-1295. Notes: Title/abstract: Excluded. Wrong study type.

Bilchick KC, Kamath S, Dimarco JP, and Stukenborg GJ. (2010) Bundle-branch block morphology and other predictors of outcome after cardiac resynchronization therapy in medicare patients. Circulation 122:2022-2030. Notes: Title/abstract: Excluded. Wrong study type.

Bilchick KC, Kamath S, Dimarco JP, and Stukenborg GJ. (2010) Bundle-branch block morphology and other predictors of outcome after cardiac resynchronization therapy in medicare patients. Revista Portuguesa de Cardiologia 29:1643-1645. Notes: Title/abstract: Excluded. Wrong study type.

Birnie D, Ha A, Higginson L, Green M, Thibault B, Wells G, and Tang A. (2011) Importance of ecg morphology in determining response to cardiac resynchronization therapy: Results from resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Canadian Journal of Cardiology 27:S242-S243. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Birnie DH, Ha A, Higginson L, Green M, Thibault B, Wells G, and Tang A. (2012) Importance of qrs duration and morphology in determining response to cardiac resynchronization therapy: Results from the resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Heart Rhythm 9:S295-S296. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Bisceglia C, Baratto F, Maccabelli G, Trevisi N, Cireddu M, Grandinetti G, and Bella PD. (2010) Effects of amiodarone treatment after ablation of ventricular tachycardia. Heart Rhythm 7:S358. Notes: Title/abstract: Excluded. Wrong study type.

Bloom HL, Constantin L, Dan D, De Lurgio DB, El-Chami M, Ganz LI, Gleed KJ, Hackett FK, Kanuru NK, Lerner DJ, Rasekh A, Simons GR, Sogade FO, and Sohail MR. (2011) Implantation success and infection in cardiovascular implantable electronic device procedures utilizing an antibacterial envelope. PACE - Pacing and Clinical Electrophysiology 34:133-142. Notes: Title/abstract: Excluded. Wrong study type.

Boehmer JP. (2003) Device therapy for heart failure. American Journal of Cardiology 91:53D-59D. Notes: Title/abstract: Excluded. Wrong study type.

Boehmer JP. (2004) CRT only or CRT plus ICD? European Heart Journal, Supplement 6:D83-D87. Notes: Title/abstract: Excluded. Wrong study type.

Boehmer JP, Carlson MD, De Marco T, Jaski BE, Higgins SL, Kennergren C, and Epstein AE. (2008) Adjudication of mortality events in a heart failure-arrhythmia trial by a multiparameter descriptive method: Comparison with methods used in heart failure trials and methods used in arrhythmia trials. Journal of Interventional Cardiac Electrophysiology 23:101-110. Notes: Title/abstract: Excluded. Wrong study type.

Bogale N, Witte K, Priori S, Cleland J, Auricchio A, Gadler F, Gitt A, Limbourg T, Linde C, Dickstein K, Fruhwald F, Strohmer B, Goethals M, Vijgen J, Trochu JN, Gras D, Kindermann M, Stellbrink C, McDonnald K, Keane D, Ben Gal T, Glikson M, Metra M, Gasparini M, Maass A, Jordaens L, Alings M, Larsen AI, Faerestrand S, Delgado J, Mont L, Persson H, Brunner-La Rocca HP, Osswald S, Squire I, and Morgan J. (2011) The European Cardiac Resynchronization Therapy Survey: Comparison of outcomes between de novo cardiac resynchronization therapy implantations and upgrades. European Journal of Heart Failure 13:974-983. Notes: Title/abstract: Excluded. Wrong study type.

Bogale N, Priori S, Cleland JGF, Brugada J, Linde C, Auricchio A, Van Veldhuisen DJ, Limbourg T, Gitt A, Gras D, Stellbrink C, Gasparini M, Metra M, Derumeaux G, Gadler F, Buga L, and Dickstein K. (2012) The European CRT Survey: 1 year (915 months) follow-up results. European Journal of Heart Failure 14:61-73. Notes: Title/abstract: Excluded. Wrong study type.

Bonanno C, Ometto R, Pasinato S, Finocchi G, La Vecchia L, and Fontanelli A. (2004) Effects of cardiac resynchronization therapy on disease progression in patients with congestive heart failure. Italian heart journal : official journal of the Italian Federation of Cardiology 5:364-370. Notes: Title/abstract: Excluded. Wrong study type.

Bonanno C, Mistrorigo F, Morato M, Ometto R, and Fontanelli A. (2010) Combined resynchronization and implantable cardioverter defibrillator therapy: Meta-analysis of randomized controlled trials. European Journal of Heart Failure, Supplement 9:S59-S60. Notes: Title/abstract: Excluded. Wrong study type.

Bonanno C, Morato M, Paccanaro M, Ometto R, and Fontanelli A. (2010) Combined resynchronization and implantable cardioverter defibrillator therapy: Meta-analysis of randomized controlled trials. European Heart Journal 31:413. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Biffi M, Martignani C, Camanini C, Grigioni F, Rapezzi C, and Branzi A. (2003) Cardioverter-defibrillators after MADIT-II: The balance between weight of evidence and treatment costs. European Journal of Heart Failure 5:419-425. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Biffi M, Martignani C, Fallani F, Greco C, Grigioni F, Corazza I, Bartolini P, Rapezzi C, Zannoli R, and Branzi A. (2004) Cardiac resynchronization by pacing: An electrical treatment of heart failure. International Journal of Cardiology 94:151-161. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Muller CP, Seidl KH, Grove R, Vogt J, Danschel W, Schuchert A, Djiane P, Biffi M, Becker T, Bailleul C, and Trappe HJ. (2006) Randomized comparison of simultaneous biventricular stimulation versus optimized interventricular delay in cardiac resynchronization therapy. The Resynchronization for the HemodYnamic Treatment for Heart Failure Management II implantable cardioverter defibrillator (RHYTHM II ICD) study. American heart journal 151:1050-1058. Notes: Title/abstract: Excluded. Wrong intervention.

Boriani G, Muller CP, Seidl KH, Grove R, Vogt J, Danschel W, Schuchert A, Djiane P, Biffi M, Becker T, Bailleul C, and Trappe HJ. (2006) Randomized comparison of simultaneous biventricular stimulation versus optimized interventricular delay in cardiac resynchronization therapy. The Resynchronization for the HemodYnamic Treatment for Heart Failure Management II implantable cardioverter defibrillator (RHYTHM II ICD) study. American heart journal 151:1057-1065. Notes: Duplicate

Boriani G, Müller CP, Seidl KH, Grove R, Vogt J, Danschel W, Schuchert A, Djiane P, Biffi M, Becker T, Bailleul C, and Trappe HJ. (2006) Randomized comparison of simultaneous biventricular stimulation versus optimized interventricular delay in cardiac resynchronization therapy. The Resynchronization

for the HemodYnamic Treatment for Heart Failure Management II implantable cardioverter defibrillator (RHYTHM II ICD) study. American. heart journal 151:1050-1058. Notes: Duplicate

Boriani G, Kranig W, Donal E, Calo L, Casella H, Ansalone G, Boulogne E, and Leclercq C. (2009) Left univentricular only pacing can be an alternative to biventricular pacing: Results of the randomized, double-blind B-LEFT HF trial. European Journal of Heart Failure, Supplement 8:ii268-ii269. Notes: Title/abstract: Excluded. Wrong intervention.

Boriani G, Biffi M, Muller CP, Seidl KH, Grove R, Vogt J, Danschel W, Schuchert A, Deharo JC, Becker T, Boulogne E, and Trappe HJ. (2009) A prospective randomized evaluation of VV delay optimization in CRT-D recipients: Echocardiographic observations from the RHYTHM II ICD study. PACE - Pacing and Clinical Electrophysiology 32:S120-S125. Notes: Title/abstract: Excluded. Wrong intervention.

Boriani G, Gasparini M, Landolina M, Lunati M, Biffi M, Santini M, Padeletti L, Molon G, Botto G, De Santo T, and Valsecchi S. (2009) Effectiveness of cardiac resynchronization therapy in heart failure patients with valvular heart disease: Comparison with patients affected by ischaemic heart disease or dilated cardiomyopathy. the InSync/InSync ICD Italian Registry. European Heart Journal 30:2275-2283. Notes: Title/abstract: Excluded. Wrong study type

Boriani G, Kranig W, Donal E, Calo L, Zecchi P, Delarche N, Lozano IF, Ansalone G, Boulogne E, and Leclercq C. (2009) Left ventricular only pacing is at least as good as biventricular pacing according to both intention to treat and per protocol analysis of the double-blind B-LEFT HF trial. European Heart Journal 30:870-871. Notes: Title/abstract: Excluded. Wrong intervention.

Boriani G, Kranig W, Donal E, Calo L, Casella M, Delarche N, Lozano IF, Ansalone G, Biffi M, Boulogne E, and Leclercq C. (2010) A randomized double-blind comparison of biventricular versus left ventricular stimulation for cardiac resynchronization therapy: The Biventricular versus Left Univentricular Pacing with ICD Back-up in Heart Failure Patients (B-LEFT HF) trial. American heart journal 159:1052-1058. Notes: Title/abstract: Excluded. Wrong intervention.

Boriani G, Diemberger I, Valzania C, Biffi M, Martignani C, Raschi E, Mantovani V, Ziacchi M, Bertini M, De Ponti F, and Branzi A. (2010) Role of drugs and devices in patients at risk of sudden cardiac death. Fundamental and Clinical Pharmacology 24:575-594. Notes: Title/abstract: Excluded. Wrong study type

Boriani G, Rapezzi C, Diemberger I, Gonzini L, Gorini M, Lucci D, Sinagra G, Cooke RMT, Di Pasquale G, Tavazzi L, and Maggioni AP. (2010) Trial-generated profiles for implantation of electrical devices in outpatients with heart failure: Real-world prevalence and 1-year outcome. Journal of Evaluation in Clinical Practice 16:82-91. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Kranig W, Donal E, Calo L, Casella M, Delarche N, Lozano IF, Ansalone G, Biffi M, Boulogne E, and Leclercq C. (2010) A randomized double-blind comparison of biventricular versus left ventricular stimulation for cardiac resynchronization therapy: the Biventricular versus Left Univentricular Pacing with ICD Back-up in Heart Failure Patients (B-LEFT HF) trial. American. heart journal 159:1052-1058. Notes: Duplicate

Boriani G, Mantovani LG, Biffi M, Schalij MJ, Martignani C, Leclercq C, Bax JJ, and Auricchio A. (2011) Cardiac resynchronization therapy: A cost or an investment? Europace 13:ii32-ii38. Notes: Title/abstract: Excluded. Wrong study type

Botto GL, Luzi M, Russo G, and Mariconti B. (2010) Cardiac resynchronization therapy with or without defibrillation backup: everything has been written? Giornale italiano di cardiologia (2006) 11:306-309. Notes: Title/abstract: Excluded. Wrong study type.

Botto GL, Boriani G, Favale S, Landolina M, Molon G, Tondo C, Biffi M, Grandinetti G, De Filippo P, Raciti G, and Padeletti L. (2011) Treatment of atrial fibrillation with a dual defibrillator in heart failure patients (TRADE HF): protocol for a randomized clinical trial. Trials 12:44. Notes: Title/abstract: Excluded. Wrong indication.

Botto GL, Boriani G, Favale S, Landolina M, Molon G, Tondo C, Biffi M, Grandinetti G, De Filippo P, Raciti G, and Padeletti L. (2011) Treatment of atrial fibrillation with a dual defibrillator in heart failure patients (TRADE HF): Protocol for a randomized clinical trial. Trials 12. Notes: Duplicate

Botto GL, Boriani G, Favale S, Landolina M, Molon G, Tondo C, Biffi M, Grandinetti G, Filippo P, Raciti G, and Padeletti L. (2011) Treatment of atrial fibrillation with a dual defibrillator in heart failure patients (TRADE HF): protocol for a randomized clinical trial. Trials 12:44. Notes: Duplicate

Bounhoure JP, Galinier M, Boveda S, and Albenque J. (2010) Ventricular arrhythmias, sudden death and heart failure. Bulletin de l'Academie Nationale de Medecine 194:997-1008. Notes: Title/abstract: Excluded. Wrong study type

Boveda S, Marijon E, Jacob S, Defaye P, Winter JB, Bulava A, Gras D, Albenque JP, Combes N, Pavin D, Delarche N, Teubl A, Lambiez M, and Chevalier P. (2009) Incidence and prognostic significance of sustained ventricular tachycardias in heart failure patients implanted with biventricular pacemakers without a back-up defibrillator: Results from the prospective, multicentre, Mona Lisa cohort study. European Heart Journal 30:1237-1244. Notes: Title/abstract: Excluded. Wrong study type.

Bover Freire R, Fernandez Lozano I, Fernandez De La Concha J, Beiras Torrado X, Monivas Palomero V, Garcia Guerrero JJ, Garcia Campo E, and Perez-Villacastin J. (2009) Early detection of heart failure decompensation by Optivol fluid status monitoring. European Heart Journal 30:308. Notes: Title/abstract: Excluded. Wrong intervention.

Bover Freire R, Perez-Caste Iln, Moreno Planas J, Morales Perez R, Zamorano Gomez JL, Ramos Isabel A, Perez-Villacastin J, and Macaya Miguel C. (2009) Prevalence and clinical management of severe left ventricular dysfunction in the general cardiology outpatient clinic. European Journal of Heart Failure, Supplement 8:ii40. Notes: Title/abstract: Excluded. Wrong study type.

Brachmann J, Bohm M, Rybak K, Klein G, Butter C, Klemm H, Schomburg R, Siebermair J, Israel C, Sinha AM, and Drexler H. (2011) Fluid status monitoring with a wireless network to reduce cardiovascular-related hospitalizations and mortality in heart failure: Rationale and design of the OptiLink HF Study (Optimization of Heart Failure Management using OptiVol Fluid Status Monitoring and Care). European Journal of Heart Failure 13:796-804. Notes: Title/abstract: Excluded. Wrong intervention.

Brachmann J, Böhm M, Rybak K, Klein G, Butter C, Klemm H, Schomburg R, Siebermair J, Israel C, Sinha AM, and Drexler H. (2011) Fluid status monitoring with a wireless network to reduce cardiovascular-related hospitalizations and mortality in heart failure: rationale and design of the OptiLink HF Study (Optimization of Heart Failure Management using OptiVol Fluid Status Monitoring and CareLink). European. Journal of Heart Failure. 13:796-804. Notes: Duplicate

Bradley DJ, Bradley EA, Baughman KL, Berger RD, Calkins H, Goodman SN, Kass DA, and Powe NR. (2003) Cardiac Resynchronization and Death from Progressive Heart Failure: A Meta-analysis of Randomized Controlled Trials. Journal of the American Medical Association 289:730-740. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail. Does not report results for NYHA class II.

Bradley DJ, Bradley EA, Baughman KL, Berger RD, Calkins H, Goodman SN, Kass DA, and Powe NR. (2003) Cardiac resynchronization and death from progressive heart failure: a meta-analysis of randomized controlled trials (Structured abstract). JAMA 289:730-740. Notes: Duplicate

Braun MU, Schnabel A, Rauwolf T, Schulze M, and Strasser RH. (2005) Impedance cardiography as a noninvasive technique for atrioventricular interval optimization in cardiac resynchronization therapy. Journal of Interventional Cardiac Electrophysiology 13:223-229. Notes: Title/abstract: Excluded. Wrong intervention.

Braunschweig F. (2007) Therapeutic and diagnostic role of electrical devices in acute heart failure. Heart Failure Reviews 12:157-166. Notes: Title/abstract: Excluded. Wrong study type

Braunschweig F, Ford I, Conraads V, Cowie MR, Jondeau G, Kautzner J, Lunati M, Munoz Aguilera R, Man Yu C, Marijianowski M, Borggrefe M, and Van Veldhuisen DJ. (2008) Can monitoring of intrathoracic impedance reduce morbidity and mortality in patients with chronic heart failure? Rationale and design of the Diagnostic Outcome Trial in Heart Failure (DOT-HF). European Journal of Heart Failure 10:907-916. Notes: Title/abstract: Excluded. Wrong intervention.

Braunschweig F, Ford I, Conraads V, Cowie MR, Jondeau G, Kautzner J, Lunati M, Munoz AR, Man YC, Marijianowski M, Borggrefe M, and Veldhuisen DJ. (2008) Can monitoring of intrathoracic impedance reduce morbidity and mortality in patients with chronic heart failure? Rationale and design of the Diagnostic Outcome Trial in Heart Failure (DOT-HF). European. Journal of Heart Failure. 10:907-916. Notes: Duplicate

Breithardt G. (2009) MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy): Cardiac resynchronization therapy towards early management of heart failure. European Heart Journal 30:2551-2553. Notes: Title/abstract: Excluded. Wrong study type.

Brenyo A, Link MS, Barsheshet A, Moss AJ, Zareba W, Wang PJ, McNitt S, Huang D, Foster E, Estes M, Solomon SD, and Goldenberg I. (2011) Cardiac resynchronization therapy reduces left atrial volume and the risk of atrial tachyarrhythmias in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). Journal of the. American. College. of Cardiology 58:1682-1689. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Bristow MR, Feldman AM, and Saxon LA. (2000) Heart failure management using implantable devices for ventricular resynchronization: Comparison of Medical Therapy, Pacing, and Defibrillation in Chronic Heart Failure (COMPANION) trial. Journal of Cardiac Failure 6:276-285. Notes: Title/abstract: Excluded. Wrong indication.

Bristow MR, Feldman AM, and Saxon LA. (2000) Heart failure management using implantable devices for ventricular resynchronization: Comparison of Medical Therapy, Pacing, and Defibrillation in Chronic Heart Failure (COMPANION) trial. COMPANION Steering Committee and COMPANION Clinical Investigators. Journal of Cardiac. Failure. 6:276-285. Notes: Duplicate

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, and Feldman AM. (2004) Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure. New England Journal of Medicine 350:2140-2150+2227. Notes: Title/abstract: Excluded. Wrong indication.

Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, Marco T, Carson P, DiCarlo L, DeMets D, White BG, DeVries DW, Feldman AM, and -Pacing. (2004) Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. The. New England. journal of medicine 350:2140-2150. Notes: Duplicate

Brown-James PR, Clark AM, Dalal H, Welch K, and Taylor RS. (2011) Patient education in the management of coronary heart disease. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Bruce GK and Friedman PA. (2005) Device-based therapies for atrial fibrillation. Current Treatment Options in Cardiovascular Medicine 7:359-370. Notes: Title/abstract: Excluded. Wrong study type.

Brugada J, Fernandez-Lozano I, Ruiz R, Berruezo A, Porres JM, Alzueta J, Zamora J, Martinez JG, and Mont L. (2009) Biventricular pacing prevents progression to heart failure in patients with ICD indication and left bundle branch block. European Heart Journal 30:280. Notes: Title/abstract: Excluded. Wrong study type.

Bruggenjurgen B, Israel CW, Klesius AA, Ezzat N, and Willich SN. (2012) Health services research in heart failure patients treated with a remote monitoring device in Germanya retrospective database analysis in evaluating resource use. Journal of Medical Economics 15:737-745. Notes: Title/abstract: Excluded. Wrong study type.

Buber J, Klein H, Moss AJ, McNitt S, Eldar M, Padeletti L, Vogt J, Meine M, Brown MW, Barsheshet A, Zareba W, and Goldenberg I. (2011) Clinical course and outcome of patients enrolled in US and non-US centres in MADIT-CRT. European Heart Journal 32:2697-2704. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Buber J, Goldenberg I, Moss AJ, Wang PJ, McNitt S, Hall WJ, Eldar M, Barsheshet A, and Shechter M. (2012) Reduction in life-threatening ventricular tachyarrhythmias in statin-treated patients with nonischemic cardiomyopathy enrolled in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). Journal of the American College of Cardiology 60:749-755. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Buber Y, Goldenberg I, Moss A, Eldar M, Glikson M, Barsheshet A, and Shechter M. (2011) Treatment with statins is associated with a reduction in ventricular fibrillation and fast ventricular tachycardia in patients with non ischemic cardiomyopathy. European Heart Journal 32:1112. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Bubien RS, Ching EA, and Kay GN. (2004) Cardiac defibrillation and resynchronization therapies: principles, therapies, and management implications. AACN clinical issues 15:340-361. Notes: Title/abstract: Excluded. Wrong study type.

Buck S, Rienstra M, Maass AH, Nieuwland W, Veldhuisen DJ, and Gelder IC. (2008) Cardiac resynchronization therapy in patients with heart failure and atrial fibrillation: importance of new-onset atrial fibrillation and total atrial conduction time. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 10:558-565. Notes: Title/abstract: Excluded. Wrong study type.

Budde T. (2006) AICD treatment in 2004 - State of the art. European Journal of Medical Research 11:432-438. Notes: Title/abstract: Excluded. Wrong study type.

Burg MR, Muthumala A, Qureshi N, Jones M, Wong K, Betts TR, Rajappan K, and Bashir Y. (2011) Pulse generator replacement as a risk factor for cardiac device infection. Pooled analysis of published studies. European Heart Journal 32:299. Notes: Title/abstract: Excluded. Wrong intervention.

Burger H, Sperzel J, Jung M, Goebel G, Walther T, and Ziegelhoeffer T. (2012) Intraoperative ICD defibrillation testing is not obsolete. Heart Rhythm 9:S106-S107. Notes: Title/abstract: Excluded. Wrong study type.

Burri H, Gerritse B, Davenport L, Demas M, and Sticherling C. (2009) Fluctuation of left ventricular thresholds and required safety margin for left ventricular pacing with cardiac resynchronization therapy. Europace 11:931-936. Notes: Title/abstract: Excluded. Wrong study type.

Burri H, Quesada A, Ricci RP, Boriani G, Davinelli M, Favale S, Da Costa A, Kautzner J, Moser R, Navarro X, and Santini M. (2010) The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) study: Rationale and design. American heart journal 160:42-48. Notes: Title/abstract: Excluded. Wrong intervention.

Burri H, Quesada A, Ricci RP, Boriani G, Davinelli M, Favale S, Costa A, Kautzner J, Moser R, Navarro X, and Santini M. (2010) The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) study: rationale and design. American. heart journal 160:42-48. Notes: Duplicate

Burri H. (2011) Cardiac resynchronization therapy for mild-to-moderate heart failure. Expert Review of Medical Devices 8:313-317. Notes: Title/abstract: Excluded. Wrong study type.

Callejo D, Guerra M, Hernandez-Madrid A, and Blasco JA. (2010) Economic assessment of cardiac resynchronization therapy. Revista Espanola de Cardiologia 63:1235-1243. Notes: Title/abstract: Excluded. Wrong study type.

Callejo D, Martin C, Guerra M, and Blasco JA. (2010) Cardiac resynchronization therapy. Economic evaluation (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

Camm AJ. (2003) Heart failure and sudden death: Future use of antiarrhythmic drugs and devices. European Heart Journal, Supplement 5:I108-I115. Notes: Title/abstract: Excluded. Wrong study type.

Camm AJ. (2004) Heart failure and sudden death: Future use of antiarrhythmic drugs and devices. European Heart Journal, Supplement 6:I108-I115. Notes: Title/abstract: Excluded. Wrong study type.

Campbell P, Takeuchi M, Bourgoun M, McNitt S, Goldenberg I, Zareba W, Moss AJ, Pfeffer MA, and Solomon SD. (2011) Relationship between change in ventricular size and function and BNP in patients undergoing CRT therapy: MADIT-CRT. Journal of Cardiac Failure 17:S57. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Campbell P, Bourgoun M, Shah A, Foster E, Brown MW, Moss AJ, Pfeffer MA, and Solomon SD. (2011) Effect of baseline right ventricular function on outcomes after CRT: An analysis of the MADIT-CRT population. Journal of the American College of Cardiology 57:E205. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT

Can I and Tholakanahalli VN. (2009) Current status of implantable cardioverter-defibrillator therapy in heart failure. Current heart failure reports 6:199-209. Notes: Title/abstract: Excluded. Wrong study type.

Cannizzaro LA, Piccini JP, Patel UD, and Hernandez AF. (2011) Device therapy in heart failure patients with chronic kidney disease. Journal of the American College of Cardiology 58:889-896. Notes: Title/abstract: Excluded. Wrong study type.

Cannom DS and Mower M. (2005) Relationship of the implantable cardioverter defibrillator and chronic resynchronization therapy: The perfect marriage? Annals of Noninvasive Electrocardiology 10:24-33. Notes: Title/abstract: Excluded. Wrong study type.

Cannom DS. (2005) Prevention of sudden cardiac death. Journal of Cardiovascular Electrophysiology 16:S21-S24. Notes: Title/abstract: Excluded. Wrong study type

Cao M, Cesario D, Gilliam FR, Powell B, Cha YM, Asirvatham S, and Saxon L. (2010) Defibrillation threshold testing (DFT) in a naturalistic practice - Results of the altitude study. Heart Rhythm 7:S7. Notes: Title/abstract: Excluded. Wrong study type.

Cappola TP, Harsch MR, Jessup M, Abraham WT, Young JB, Petersen-Stejskal S, Plappert T, and John Sutton M. (2006) Predictors of Remodeling in the CRT Era: Influence of Mitral Regurgitation, BNP, and Gender. Journal of Cardiac Failure 12:182-188. Notes: Title/abstract: Excluded. Wrong study type.

Carroll SL, Browne G, McGillion M, and Arthur HM. (2012) One-year adjustment to a prophylactic defibrillator is influenced by early device complications and poor mental health. Canadian Journal of Cardiology 28:S335. Notes: Title/abstract: Excluded. Wrong study type.

Carroll SL, McGillion M, Browne G, and Arthur HM. (2012) One-year defibrillator adjustment is influenced by early device complications and poor mental health in primary prevention patients. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Carson P, Anand I, O'Connor C, Jaski B, Steinberg J, Lwin A, Lindenfeld J, Ghali J, Barnet JH, Feldman AM, and Bristow MR. (2005) Mode of death in advanced heart failure: The Comparison of Medical, Pacing, and Defibrillation Therapies in Heart Failure (COMPANION) trial. Journal of the American College of Cardiology 46:2329-2334. Notes: Title/abstract: Excluded. Wrong indication.

Casey C and Knight BP. (2004) Cardiac resynchronization pacing therapy. Cardiology 101:72-78. Notes: Title/abstract: Excluded. Wrong study type.

Cesario DA, Turner JW, and Dec GW. (2007) Biventricular Pacing and Defibrillator Use in Chronic Heart Failure. Cardiology Clinics 25:595-603. Notes: Title/abstract: Excluded. Wrong study type.

Cevik C, Nugent K, Perez-Verdia A, and Fish RD. (2010) Prophylactic implantation of cardioverter defibrillators in idiopathic nonischemic cardiomyopathy for the primary prevention of death: A narrative review. Clinical Cardiology 33:254-260. Notes: Title/abstract: Excluded. Wrong study type.

Cha YM, Chareonthaitawee P, Dong YX, Kemp BJ, Oh JK, Miyazaki C, Hayes DL, Rea RF, Asirvatham SJ, Webster TL, Dalzell CM, Hodge DO, Herges RM, Yong YZ, Zhang Y, and Chen PS. (2011) Cardiac sympathetic reserve and response to cardiac resynchronization therapy. Circulation: Heart Failure 4:339-344. Notes: Title/abstract: Excluded. Wrong study type.

Chachques JC, Shafy A, Duarte F, Cattadori B, Goussef N, Shen L, and Carpentier A. (2002) From dynamic to cellular cardiomyoplasty. Journal of Cardiac Surgery 17:194-200. Notes: Title/abstract: Excluded. Wrong study type

Champagne J, Healey JS, Krahn AD, Philippon F, Gurevitz O, Swearingen A, and Glikson M. (2011) The effect of electronic repositioning on left ventricular pacing and phrenic nerve stimulation. Europace 13:409-415. Notes: Title/abstract: Excluded. Wrong study type.

Chandrasekaran B and Cowburn PJ. (2010) Heart failure: The challenge of selecting patients for implantable cardioverter defibrillator therapy. Expert Review of Medical Devices 7:461-467. Notes: Title/abstract: Excluded. Wrong study type.

Chapa DW, Lee HJ, Kao CW, Friedmann E, Thomas SA, Anderson J, and Bardy GH. (2008) Reducing mortality with device therapy in heart failure patients without ventricular arrhythmias. American journal of critical care : an official publication, American Association of Critical-Care Nurses 17:443-452. Notes: Title/abstract: Excluded. Wrong study type.

Charlton TA, McGrew FA, Johnson EE, Coppess MA, Hamilton B, Charlton SB, and Sims JJ. (2009) Defibrillator utilization rates in 234 elderly patients receiving cardiac resynchronization therapy. Journal of Cardiac Failure 15:S60. Notes: Title/abstract: Excluded. Wrong study type.

Charlton TA, Johnson EE, Coppess MA, McGrew FA, Hamilton B, Charlton SB, and Sims JJ. (2009) Cardiac resynchronization therapy-defibrillator utilization rates in 234 elderly patients at a single center. European Heart Journal 30:559. Notes: Title/abstract: Excluded. Wrong study type.

Chauvin M. (2006) The best of cardiac pacing in 2005. Archives des Maladies du Coeur et des Vaisseaux 99:79-84. Notes: Title/abstract: Excluded. Wrong study type.

Chen EA, Patel-Raman SM, O'Callaghan K, and Hillebrenner MG. (2009) FDA'S perspectives on cardiovascular devices. Journal of Cardiovascular Translational Research 2:143-146. Notes: Title/abstract: Excluded. Wrong study type

Chen S, Yin Y, and Krucoff MW. (2012) Effect of cardiac resynchronization therapy and implantable cardioverter defibrillator on quality of life in patients with heart failure: A meta-analysis. Europace 14:1602-1607. Notes: Title/abstract: Included. Full text: Included. SR

Cheng A, Wang Y, Curtis JP, and Varosy PD. (2010) Acute lead dislodgements and in-hospital mortality in patients enrolled in the national cardiovascular data registry implantable cardioverter defibrillator registry. Journal of the American College of Cardiology 56:1651-1656. Notes: Title/abstract: Excluded. Wrong study type.

Cheng Z, Zei PC, Hsia HH, Al-Almad A, Turakhia M, Daubert J, Zareba W, Moss AJ, and Wang PJ. (2010) One train of antitachycardia pacing is successful for fast ventricular tachycardia in patients with conduction abnormalities and left ventricular dysfunction: Results from the MADIT-CRT study. Heart Rhythm 7:S302. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Choucair WK, Lip GY, Waldo AL, Bersohn MM, Martin DT, Akar JG, Wathen M, Neve N, Halperin JL, and Ip J. (2012) Atrial arrhythmias in ICD versus CRT-D subjects. Circulation 126. Notes: Title/abstract: Excluded. Wrong intervention.

Chung ES, Menon SG, Weiss R, Schloss EJ, Chow T, Kereiakes DJ, Mazur W, Salo RW, Galle E, and Pastore JM. (2007) Feasibility of biventricular pacing in patients with recent myocardial infarction: impact on ventricular remodeling. Congestive heart failure (Greenwich, Conn.) 13:9-15. Notes: Title/abstract: Excluded. Wrong indication.

Chung ES, Menon SG, Weiss R, Schloss EJ, Chow T, Kereiakes DJ, Mazur W, Salo RW, Galle E, and Pastore JM. (2007) Feasibility of biventricular pacing in patients with recent myocardial infarction: impact on ventricular remodeling. Congestive. heart failure. 13:9-15. Notes: Duplicate

Chung ES, Dan D, Solomon SD, Bank AJ, Pastore J, Iyer A, Berger RD, Franklin JO, Jones G, MacHado C, and Stolen CM. (2010) Effect of peri-infarct pacing early after myocardial infarction results of the prevention of myocardial enlargement and dilatation post myocardial infarction study. Circulation: Heart Failure 3:650-658. Notes: Title/abstract: Excluded. Wrong indication.

Chung ES, Dan D, Solomon SD, Bank AJ, Pastore J, Iyer A, Berger RD, Franklin JO, Jones G, MacHado C, and Stolen CM. (2010) Effect of peri-infarct pacing early after myocardial infarction: results of the prevention of myocardial enlargement and dilatation post myocardial infarction study. Circulation. Heart failure. 3:650-658. Notes: Duplicate

Clarke B and Howlett J. (2012) Integration of monitoring technology for heart failure. Current Opinion in Cardiology 27:130-136. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JG, Daubert JC, Erdmann E, Freemantle N, Gras D, Kappenberger L, and Tavazzi L. (2006) Longer-term effects of cardiac resynchronization therapy on mortality in heart failure [the CArdiac REsynchronization-Heart Failure (CARE-HF) trial extension phase]. European. Heart Journal 27:1928-1932. Notes: Title/abstract: Excluded. Wrong indication.

Cleland JG, Cullington D, Khaleva O, and Tageldien A. (2008) Cardiac resynchronization therapy: dyssynchrony imaging from a heart failure perspective. Current Opinion in Cardiology 23:634-645. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JG, Buga L, Ghosh J, and Nasir M. (2010) Applying evidence-based device care in cardiovascular patients: Which patient with heart failure and what device? Journal of the Royal College of Physicians of Edinburgh 40:229-239. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF, Thackray S, Goodge L, Kaye G, and Cooklin M. (2002) Outcome studies with device therapy in patients with heart failure. Journal of Cardiovascular Electrophysiology 13:S73-S91. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Ghosh J, Khan N, Hurren S, and Kaye G. (2003) Ongoing trials of cardiac resynchronisation. Minerva Cardioangiologica 51:197-207. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Coletta AP, Nikitin N, Louis A, and Clark A. (2003) Update of clinical trials from the American College of Cardiology 2003. EPHESUS, SPORTIF-III, ASCOT, COMPANION, UK-PACE and T-wave alternans. European Journal of Heart Failure 5:391-398. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF, Ghosh J, Freemantle N, Kaye GC, Nasir M, Clark AL, and Coletta AP. (2004) Clinical trials update and cumulative meta-analyses from the American College of Cardiology: WATCH, SCD-HeFT, DINAMIT, CASINO, INSPIRE, STRATUS-US, RIO-LIPIDS and cardiac resynchronisation therapy in heart failure. European Journal of Heart Failure 6:501-508. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Coletta AP, Lammiman M, Witte KK, Loh H, Nasir M, and Clark AL. (2005) Clinical trials update from the European Society of Cardiology meeting 2005: CARE-HF extension study, ESSENTIAL, CIBIS-III, S-ICD, ISSUE-2, STRIDE-2, SOFA, IMAGINE, PREAMI, SIRIUS-II and ACTIVE. European Journal of Heart Failure 7:1070-1075. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Coletta AP, Yassin A, Hado H, Cullington D, Abdellah AT, and Clark AL. (2008) Clinical trials update from the American College of Cardiology 2008: CARISMA, TRENDS, meta-analysis of Cox-2 studies, HAT, ON-TARGET, HYVET, ACCOMPLISH, MOMENTUM, PROTECT, HORIZON-HF and REVERSE. European Journal of Heart Failure 10:614-620. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Tageldien A, Maarouf N, and Hobson N. (2008) Patients with heart failure who require an implantable defibrillator should have cardiac resynchronisation routinely. Heart 94:963-966. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF, Coletta AP, Yassin A, Buga L, Torabi A, and Clark AL. (2009) Clinical trials update from the European Society of Cardiology Meeting 2009: AAA, RELY, PROTECT, ACTIVE-I, European CRT survey, German pre-SCD II registry, and MADIT-CRT. European Journal of Heart Failure 11:1214. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF, Coletta AP, Clark AL, and Cullington D. (2009) Clinical trials update from the American College of Cardiology 2009: ADMIRE-HF, PRIMA, STICH, REVERSE, IRIS, partial ventricular support, FIX-HF-5, vagal stimulation, REVIVAL-3, pre-RELAX-AHF, ACTIVE-A, HF-ACTION, JUPITER, AURORA, and OMEGA. European Journal of Heart Failure 11:622-630. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Coletta AP, Buga L, Ahmed D, and Clark AL. (2010) Clinical trials update from the American College of Cardiology meeting 2010: DOSE, ASPIRE, CONNECT, STICH, STOP-AF, CABANA, RACE II, EVEREST II, ACCORD, and NAVIGATOR. European Journal of Heart Failure 12:623-629. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Coletta AP, Buga L, Antony R, Pellicori P, Freemantle N, and Clark AL. (2011) Clinical trials update from the American Heart Association Meeting 2010: EMPHASIS-HF, RAFT, TIM-HF, Tele-HF, ASCEND-HF, ROCKET-AF, and PROTECT. European Journal of Heart Failure 13:460-465. Notes: Title/abstract: Excluded. Wrong study type.

Clemo HF, Saberi L, Cycan A, and Doshi SK. (2010) Differences in optimal pulse width for ICD waveform optimization between ischemic and non-ischemic patients. Europace 12:i95. Notes: Title/abstract: Excluded. Wrong study type.

Coats CJ and Elliott PM. (2008) Current management of hypertrophic cardiomyopathy. Current Treatment Options in Cardiovascular Medicine 10:496-504. Notes: Title/abstract: Excluded. Wrong study type.

Coletta AP, Clark AL, Seymour AML, and Cleland JGF. (2003) Clinical trials update from the European Society of Cardiology Heart Failure meeting: COMET, COMPANION, tezosentan and SHAPE. European Journal of Heart Failure 5:545-548. Notes: Title/abstract: Excluded. Wrong study type

Conraads VM, Tavazzi L, Santini M, Oliva F, Gerritse B, Yu CM, and Cowie MR. (2010) Results of a prospective trial to assess sensitivity and positive predictive value of implantable intrathoracic impedance monitoring in the prediction of heart failure hospitalizations: SENSE-HF trial. European Journal of Heart Failure, Supplement 9:S27. Notes: Title/abstract: Excluded. Wrong intervention.

Conraads VM, Tavazzi L, Santini M, Oliva F, Gerritse B, Yu CM, and Cowie MR. (2011) Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: The SENSE-HF trial. European Heart Journal 32:2266-2273. Notes: Title/abstract: Excluded. Wrong intervention.

Contractor TA, Michowitz Y, Bourke T, and Shivkumar K. (2010) Should defibrillation threshold be tested in patients with cardiac resynchronization therapy-defibrillator implantation? Journal of the American College of Cardiology 55:A12. Notes: Title/abstract: Excluded. Wrong study type.

Costa FM, Morgado FB, Cavaco D, Santos PG, Oliveira S, Almeida S, Miranda R, Carmo P, and Adragao P. (2011) CRT-D: Outcomes after appropriate therapy. Journal of Cardiovascular Electrophysiology 22:S149. Notes: Title/abstract: Excluded. Wrong study type

Crawford-Faucher A. (2010) Home- and center-based cardiac rehabilitation equally effective. American Family Physician 82:994-995. Notes: Title/abstract: Excluded. Wrong intervention.

Croshaw R, Kim Y, Lappinen E, Julian T, and Trombetta M. (2011) Avoiding mastectomy: Accelerated partial breast irradiation for breast cancer patients with pacemakers or defibrillators. Annals of Surgical Oncology 18:3500-3505. Notes: Title/abstract: Excluded. Wrong study type.

Crossley G, Boyle A, Vitense H, Sherfesee L, and Mead RH. (2008) Trial design of the clinical evaluation of remote notification to reduce time to clinical decision: The Clinical evaluation Of remote NotificatioN to rEduCe Time to clinical decision (CONNECT) study. American heart journal 156:840-846. Notes: Title/abstract: Excluded. Wrong intervention.

Crossley G, Boyle A, Vitense H, Sherfesee L, and Mead RH. (2008) Trial design of the clinical evaluation of remote notification to reduce time to clinical decision: the Clinical evaluation Of remote NotificatioN to rEduCe Time to clinical decision (CONNECT) study. American. heart journal 156:840-846. Notes: Duplicate

Crossley G, Hardwin Mead R, Sheldon T, Chang Y, Vitense HS, and Boyle A. (2010) Left Ventricular Capture Management is useful in the management of left ventricular thresholds. Europace 12:i148. Notes: Title/abstract: Excluded. Wrong intervention.

Crossley GH, Mead H, Kleckner K, Sheldon T, Davenport L, Harsch MR, Parikh P, Ramza B, Fishel R, and Bailey JR. (2007) Automated left ventricular capture management. PACE - Pacing and Clinical Electrophysiology 30:1190-1200. Notes: Title/abstract: Excluded. Wrong study type.

Crossley GH, Aonuma K, Haffajee C, Shoda M, Meijer A, Bauer A, Boriani G, Svendsen J, Thomas S, Wiggenhorn C, and Unterberg-Buchwald C. (2009) Atrial fibrillation therapy in patients with a CRT defibrillator with wireless telemetry. PACE - Pacing and Clinical Electrophysiology 32:13-23. Notes: Title/abstract: Excluded. Wrong study type.

Crossley GH, Boyle A, Vitense H, Chang Y, and Mead RH. (2011) The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: The value of wireless remote monitoring with automatic clinician alerts. Journal of the American College of Cardiology 57:1181-1189. Notes: Title/abstract: Excluded. Wrong intervention.

Crossley GH, Boyle A, Vitense H, Chang Y, and Mead RH. (2011) The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. Journal of the. American. College. of Cardiology 57:1181-1189. Notes: Duplicate

Cuculich PS and Joseph S. (2011) Cardiac resynchronization therapy: What? Who? When? How? American Journal of Medicine 124:813-815. Notes: Title/abstract: Excluded. Wrong study type.

Curtis AB. (2006) Are women worldwide under-treated with regard to cardiac resynchronization and sudden death prevention? Journal of Interventional Cardiac Electrophysiology 17:169-175. Notes: Title/abstract: Excluded. Wrong study type.

Curtis AB, Adamson PB, Chung E, John Sutton MS, Tang F, and Worley S. (2007) Biventricular versus right ventricular pacing in patients with AV block (BLOCK HF): Clinical study design and rationale. Journal of Cardiovascular Electrophysiology 18:965-971. Notes: Title/abstract: Excluded. Wrong intervention.

Curtis AB, Fonarow GC, Yancy CW, Albert NM, Gattis Stough W, Gheorghiade M, Heywood JT, McBride ML, Mehra M, O'Connor C, Reynolds D, and Walsh MN. (2009) Influence of atrial fibrillation on the use of CRT and ICD therapy in heart failure: Findings from IMPROVE HF. Journal of Cardiac Failure 15:S64. Notes: Title/abstract: Excluded. Wrong study type.

Curtis AB, Yancy CW, Albert NM, Stough WG, Gheorghiade M, Heywood JT, McBride ML, Mehra MR, OConnor CM, Reynolds D, Walsh MN, and Fonarow GC. (2009) Cardiac resynchronization therapy utilization for heart failure: Findings from IMPROVE HF. American heart journal 158:956-964. Notes: Title/abstract: Excluded. Wrong study type.

Curtis AB and Narasimha D. (2012) Arrhythmias in women. Clinical Cardiology 35:166-171. Notes: Title/abstract: Excluded. Wrong study type.

Czuriga I. (2005) Chronic heart failure - An epidemic of the 21 st century. Orvosi hetilap 146:1075-1087. Notes: Title/abstract: Excluded. Wrong study type.

Dadous G and Sakantamis G. (2010) The use of ICD's, bivent. P and LVAD's in non ischemic DCM. Epitheorese Klinikes Farmakologias kai Farmakokinetikes 28:193-195. Notes: Title/abstract: Excluded. Wrong study type.

Darondel JM and Sebbah J. (2008) PM or ICD in cardiac resynchronisation therapy. Medecine Therapeutique - Cardio 4:25-37. Notes: Title/abstract: Excluded. Wrong study type.

Das M. (2009) Indications for ICD and cardiac resynchronization therapy for prevention of sudden cardiac death. Expert Review of Cardiovascular Therapy 7:181-195. Notes: Title/abstract: Excluded. Wrong study type.

Daubert C, Gold MR, Abraham WT, Ghio S, Hassager C, Goode G, Szili-Torok T, and Linde C. (2009) Prevention of Disease Progression by Cardiac Resynchronization Therapy in Patients With Asymptomatic or Mildly Symptomatic Left Ventricular Dysfunction. Insights From the European Cohort of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) Trial. Journal of the American College of Cardiology 54:1837-1846. Notes: Title/abstract: Included. Full text: Included. REVERSE

Daubert C, Gold MR, Abraham WT, Ghio S, Hassager C, Goode G, Szili TT, and Linde C. (2009) Prevention of disease progression by cardiac resynchronization therapy in patients with asymptomatic or mildly symptomatic left ventricular dysfunction: insights from the European cohort of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) trial. Journal of the. American. College. of Cardiology 54:1837-1846. Notes: Duplicate

Daubert JC, Leclercq C, and Mabo P. (2005) There is plenty of room for cardiac resynchronization therapy devices without back-up defibrillators in the electrical treatment of heart failure. Journal of the American College of Cardiology 46:2204-2207. Notes: Title/abstract: Excluded. Wrong study type

Daubert JC, Leclercq C, Donal E, and Mabo P. (2006) Cardiac resynchronisation therapy in heart failure: Current status. Heart Failure Reviews 11:147-154. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JC, Donal E, and Linde C. (2012) A plea for the wider use of CRT-P in candidates for cardiac resynchronisation therapy. Heart Failure Reviews 17:767-775. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JP, Hranitzky PM, McNitt S, Klein HU, Gold MR, Wilber DJ, Brown M, Cannom DS, Zareba W, and Moss AJ. (2011) MADIT-CRT: Resynchronization patients experience more complications than ICD-Only patients but outcomes are not significantly impacted. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Daubert JP, Wang PJ, Huang DT, McNitt SA, uger CD, Brown MW, Cannom DS, Moss AJ, and Zareba W. (2011) Inappropriate shocks in madit-CRT: Predictors and outcome. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Davies EJ, Moxham T, Rees K, Singh S, Coats-Andrew JS, Ebrahim S, Lough F, and Taylor RS. (2010) Exercise based rehabilitation for heart failure. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Davies P, Taylor F, Beswick A, Wise F, Moxham T, Rees K, and Ebrahim S. (2010) Promoting patient uptake and adherence in cardiac rehabilitation. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Davy JM, Tri Cung T, Cransac F, Massin F, Tapiero A, Roubille F, and Pasquie JL. (2011) Permanent Atrial Fibrillation. Archives of Cardiovascular Diseases Supplements 3:225-235. Notes: Title/abstract: Excluded. Wrong study type

Day JD, Doshi RN, Belott P, Birgersdotter-Green U, Behboodikhah M, Ott P, Glatter KA, Tobias S, Frumin H, Lee BK, Merillat J, Wiener I, Wang S, Grogin H, Chun S, Patrawalla R, Crandall B, Osborn JS, Weiss JP, Lappe DL, and Neuman S. (2007) Inductionless or limited shock testing is possible in most patients with implantable cardioverter-defibrillators/cardiac resynchronization therapy defibrillators: Results of the multicenter ASSURE Study (Arrhythmia Single Shock Defibrillation Threshold Testing Versus Upper Limit of Vulnerability: Risk Reduction Evaluation with Implantable Cardioverter-Defibrillator Implantations). Circulation 115:2382-2389. Notes: Title/abstract: Excluded. Wrong intervention.

Day JD, Doshi RN, Belott P, Birgersdotter GU, Behboodikhah M, Ott P, Glatter KA, Tobias S, Frumin H, Lee BK, Merillat J, Wiener I, Wang S, Grogin H, Chun S, Patrawalla R, Crandall B, Osborn JS, Weiss JP, Lappe DL, and Neuman S. (2007) Inductionless or limited shock testing is possible in most patients with implantable cardioverter- defibrillators/cardiac resynchronization therapy defibrillators: results of the multicenter ASSURE Study (Arrhythmia Single Shock Defibrillation Threshold Testing Versus Upper Limit of Vulnerability: Risk Reduction Evaluation With Implantable Cardioverter-Defibrillator Implantations). Circulation 115:2382-2389. Notes: Duplicate

De Berrazueta Fernandez JR. (2006) Chronic heart failure treatment in the year 2006. Anales de la Real Academia Nacional de Medicina 123:617-630. Notes: Title/abstract: Excluded. Wrong study type.

De Bono JP, Ruperalia N, Nizar S, Bashir Y, Betts TR, and Rajappan K. (2009) Antibiotic prophylaxis during device implantation, a UK perspective. Heart Rhythm 6:S444-S445. Notes: Title/abstract: Excluded. Wrong study type.

De Marco T, Wolfel E, Feldman AM, Lowes B, Higginbotham MB, Ghali JK, Wagoner L, Kirlin PC, Kennett JD, Goel S, Saxon LA, Boehmer JP, Mann D, Galle E, Ecklund F, Yong P, and Bristow MR. (2008) Impact of Cardiac Resynchronization Therapy on Exercise Performance, Functional Capacity, and Quality of Life in Systolic Heart Failure With QRS Prolongation: COMPANION Trial Sub-Study. Journal of Cardiac Failure 14:9-18. Notes: Title/abstract: Excluded. Wrong indication.

Deering TF, Epstein AE, Goldman DS, Greenberg S, and Dalal YH. (2010) 2 year total and specific-cause mortality rates among the 6129 ICD and CRT-D patients in the advancements in ICD therapy (ACT) registry. Europace 12:i25. Notes: Title/abstract: Excluded. Wrong study type.

Defaye P, Lazarus A, Lande G, Mondoly P, Gras D, Dupuis M, Delarche N, Bizeau O, Mouton E, and Sadoul N. (2011) Defibrillation testing at implant and clinical outcomes in ICD patients: A prospective, multicenter study (leader). European Heart Journal 32:478. Notes: Title/abstract: Excluded. Wrong intervention.

Deneke T, Von Dryander S, Grewe PH, and Lemke B. (2004) Medical therapy for chronic heart failure. Herzschrittmachertherapie und Elektrophysiologie 15:I/74-I/80. Notes: Title/abstract: Excluded. Wrong study type.

Denollet J, Tekle FB, Pedersen SS, Van Der Voort PH, Alings M, and Van Den Broek KC. (2012) Prognostic importance of distressed (Type D) personality and shocks in patients with an implantable cardioverter defibrillator. International Journal of Cardiology. Notes: Title/abstract: Excluded. Wrong study type.

Desai AD, Burke MC, Hong TE, Kim S, Salem Y, Yong PG, and Knight BP. (2006) Predictors of appropriate defibrillator therapy among patients with an implantable defibrillator that delivers cardiac resynchronization therapy. Journal of Cardiovascular Electrophysiology 17:486-490. Notes: Title/abstract: Excluded. Wrong study type.

Desai AD, Burke MC, Hong TE, Kim S, Salem Y, Yong PG, and Knight BP. (2006) Predictors of appropriate defibrillator therapy among patients with an implantable defibrillator that delivers cardiac resynchronization therapy. Journal of cardiovascular. electrophysiology. 17:486-490. Notes: Duplicate

Desai AS, Fang JC, Maisel WH, and Baughman KL. (2004) Implantable defibrillators for the prevention of mortality in patients with nonischemic cardiomyopathy: A meta-analysis of randomized controlled trials. Journal of the American Medical Association 292:2874-2879. Notes: Title/abstract: Excluded. Wrong indication.

Desai AS, Fang JC, Maisel WH, and Baughman KL. (2004) Implantable defibrillators for the prevention of mortality in patients with nonischemic cardiomyopathy: a meta-analysis of randomized controlled trials (Structured abstract). JAMA 292:2874-2879. Notes: Duplicate

Desai H, Aronow WS, Ahn C, Tsai FS, Lai HM, Gandhi K, Amin H, Frishman WH, Kalapatapu K, Cohen M, and Sorbera C. (2010) Incidence of appropriate cardioverter-defibrillator shocks and mortality in patients with heart failure treated with combined cardiac resynchronization plus implantable cardioverter-defibrillator therapy versus implantable cardioverter-defibrillator therapy. Journal of Cardiovascular Pharmacology and Therapeutics 15:37-40. Notes: Title/abstract: Excluded. Wrong study type.

Deshmukh PM, Deshmukh A, Romanyshyn M, Anderson K, Lahoda D, Lambert P, and Babayan Z. (2009) Comparasion of direct his bundle and biventricular pacing. Heart Rhythm 6:S375-S376. Notes: Title/abstract: Excluded. Wrong study type.

Di Giovine G, Cavallino C, Leva L, Brambilla M, and Marino P. (2011) LV dyssynchrony as assessed with 2D echo time-to-peak or TUS at longitudinal, circumferential, and radial level and with gated myocardial perfusion spect phase analysis do not predict response to CRT. Giornale Italiano di Cardiologia 12:e117. Notes: Title/abstract: Excluded. Wrong study type.

Diab I, Kamdar R, Hunter R, Berriman T, Abrams D, Dhinoja M, Earley M, Sporton S, and Schilling R. (2010) Value of echocardiographic mechanical dyssynchrony assessment in selecting patients for cardiac resynchronization therapy. Journal of Interventional Cardiac Electrophysiology 27:182. Notes: Title/abstract: Excluded. Wrong indication.

Diab IG, Kamdar R, Hunter R, Berriman T, Duncan E, Abrams D, Dhinoja M, Earley M, Sporton S, and Schilling R. (2010) Value of echocardiographic mechanical dyssynchrony assessment in selecting patients for cardiac resynchronisation therapy. Heart Rhythm 7:S370-S371. Notes: Title/abstract: Excluded. Wrong indication.

Diab IG, Hunter RJ, Kamdar R, Berriman T, Duncan E, Richmond L, Baker V, Abrams D, Earley MJ, Sporton S, and Schilling RJ. (2011) Does ventricular dyssynchrony on echocardiography predict response to cardiac resynchronisation therapy? A randomised controlled study. Heart 97:1410-1416. Notes: Title/abstract: Excluded. Wrong indication.

Diab IG, Hunter RJ, Kamdar R, Berriman T, Duncan E, Richmond L, Baker V, Abrams D, Earley MJ, Sporton S, and Schilling RJ. (2011) Does ventricular dyssynchrony on echocardiography predict response to cardiac resynchronisation therapy? A randomised controlled study. Heart 97:1410-1416. Notes: Duplicate

Dickstein K, Bogale N, Priori S, Auricchio A, Cleland JG, Gitt A, Limbourg T, Linde C, Van Veldhuisen DJ, and Brugada J. (2009) The European cardiac resynchronization therapy survey. European Heart Journal 30:2450-2460. Notes: Title/abstract: Excluded. Wrong study type.

Dilaveris P, Giannopoulos G, Synetos A, Aggeli C, Raftopoulos L, Arsenos P, Gatzoulis K, and Stefanadis C. (2009) Effect of biventricular pacing on ventricular repolarization and functional indices in patients with heart failure: Lack of association with arrhythmic events. Europace 11:741-750. Notes: Title/abstract: Excluded. Wrong study type.

Dimarco JP. (2003) Implantable Cardioverter-Defibrillators. New England Journal of Medicine 349:1836-1847. Notes: Title/abstract: Excluded. Wrong study type.

Ding L, Hua W, Niu H, Chen K, and Zhang S. (2008) Primary prevention of sudden cardiac death using implantable cardioverter defibrillators. Europace 10:1034-1041. Notes: Title/abstract: Excluded. Wrong study type

Djiane P. (2004) The Best of Cardiac Pacing in 2003. Archives des Maladies du Coeur et des Vaisseaux 97:55-61. Notes: Title/abstract: Excluded. Wrong study type.

Dohadwala M, Mark Estes III NA, and Link MS. (2011) New paradigms in the prevention of sudden cardiac arrest and heart failure treatment. Current Cardiology Reports 13:377-386. Notes: Title/abstract: Excluded. Wrong study type

Doll N, Piorkowski C, Czesla M, Kallenbach M, Rastan AJ, Arya A, and Mohr FW. (2008) Epicardial versus transvenous left ventricular lead placement in patients receiving cardiac resynchronization therapy: results from a randomized prospective study. The. Thoracic. and cardiovascular. surgeon. 56:256-261. Notes: Title/abstract: Excluded. Wrong intervention.

Donahue T, Niazi I, Leon A, Stucky M, and Herrmann K. (2012) Acute and chronic response to CRT in narrow QRS patients. Journal of Cardiovascular Translational Research 5:232-241. Notes: Title/abstract: Excluded. Wrong study type.

Dong K, Shen WK, Powell BD, Dong YX, Rea RF, Friedman PA, Hodge DO, Wiste HJ, Webster T, Hayes DL, and Cha YM. (2010) Atrioventricular nodal ablation predicts survival benefit in patients with atrial fibrillation receiving cardiac resynchronization therapy. Heart Rhythm 7:1240-1245. Notes: Title/abstract: Excluded. Wrong study type.

Dong Y, Burnett J, Chen HH, Sandberg S, Yang Y, Zhang Y, Chen PS, and Cha YM. (2011) Effect of cardiac resynchronization therapy on broad neurohormone biomarkers in heart failure. Journal of Interventional Cardiac Electrophysiology1-9. Notes: Title/abstract: Excluded. Wrong study type.

Dong YX, Burnett JC, Chen HH, Sandberg S, Zhang Y, Chen PS, and Cha YM. (2010) The effect of cardiac resynchronisation therapy on novel neurohormones in heart failure. Heart 96:A192-A193. Notes: Title/abstract: Excluded. Wrong study type.

Dong YX, Burnett J, Chen HH, Sandberg S, Yang YZ, Zhang Y, Chen PS, and Cha YM. (2011) Effect of cardiac resynchronization therapy on broad neurohormone biomarkers in heart failure. Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing 30:241-249. Notes: Duplicate

Dong YX, Burnett JC, Chen HH, Sandberg S, Zhang Y, Chen PS, and Cha YM. (2011) The effect of cardiac resynchronization therapy on novel neurohormones in heart failure. Europace 13:i70. Notes: Title/abstract: Excluded. Wrong study type.

Dosdall DJ and Ideker RE. (2005) New technologies of internal defibrillation. Journal of Interventional Cardiac Electrophysiology 13:67-70. Notes: Title/abstract: Excluded. Wrong study type

Doshi SK, Val-Mejias JE, Pittaro M, Reeves R, Shah S, and Lee K. (2009) Comparison of defibrillation thresholds using nulltunednull waveforms at different right ventricular lead locations. Heart Rhythm 6:S374. Notes: Title/abstract: Excluded. Wrong study type.

Doshi SK, Val-Mejias JE, Pittaro M, Reeves R, Payne J, Henthorn R, Hong M, Zweibel S, Kroll M, Graumann R, and Oza AL. (2009) Do similar t-shock and rescue shock waveforms, when altered, affect ulv based dft estimations? Heart Rhythm 6:S438. Notes: Title/abstract: Excluded. Wrong intervention.

Doshi SK, Oza AL, Lee LY, and Pradhan S. (2010) Predictors of high DFT in patients with programmable waveform ICDS. Heart Rhythm 7:S428. Notes: Title/abstract: Excluded. Wrong study type.

Doshi SK, Pittaro MD, Reeves R, Boyce K, Payne JP, Kroll MW, Graumann RJ, Oza AL, and Val-Mejias JE. (2012) Efficacy of tuned waveforms based on different membrane time constants on defibrillation thresholds: Primary results from the POWER trial. PACE - Pacing and Clinical Electrophysiology 35:1253-1261. Notes: Title/abstract: Excluded. Wrong intervention.

Ducharme A, Prylutska H, Harel F, O'Meara E, Lavoie J, Frasure-Smith N, Mansour A, White M, and Thibault B. (2011) Absence of remodeling benefit of LV-CRT over BV-CRT in patients with heart failure and wide QRS: Insight from the evaluation of resynchronization therapy for heart failure (EARTH) trial. Circulation 124. Notes: Title/abstract: Excluded. Wrong intervention.

Ducharme A, Prylutska H, Harel F, O'Meara E, Lavoie J, White M, and Thibault B. (2011) Similar remodeling benefit of LV-CRT and BIV-CRT in patients with heart failure and wide qrs: Insight from the evaluation of resynchronization therapy for heart failure (EARTH) trial. Canadian Journal of Cardiology 27:S248. Notes: Title/abstract: Excluded. Wrong intervention.

Ducharme A, Prylutska H, Harel F, O'Meara E, Frasure-Smith N, White M, and Thibault B. (2011) Absence of remodeling benefit of LV-CRT over BiV-CRT in patients with heart failure and wide QRS: Insight from the evaluation of resynchronization therapy for heart failure (EARTH) trial. Journal of Heart and Lung Transplantation 30:S49. Notes: Title/abstract: Excluded. Wrong intervention.

Duparc A, Rollin, Boveda S, Mondoly P, Combes N, Hebrard A, Delay M, Maury P, and Albenque JP. (2010) Cardiac Resynchronization Therapy in elderly patients. Europace 12:i155. Notes: Title/abstract: Excluded. Wrong study type.

Duray GZ, Israel CW, Pajitnev D, and Hohnloser SH. (2008) Upgrading to biventricular pacing/defibrillation systems in right ventricular paced congestive heart failure patients: Prospective assessment of procedural parameters and response rate. Europace 10:48-52. Notes: Title/abstract: Excluded. Wrong study type.

Duro L, Santini L, Doldo V, Forleo GB, Magliano G, Papavasileiou LP, Cioe R, Sgueglia M, Babuscio G, De Stefano M, Ticconi F, and Romeo F. (2011) Ropivacaine-lidocaine combination as a local anesthesia during pacemaker and implantable cardioverter-defibrillator implantation. Giornale Italiano di Cardiologia 12:e226. Notes: Title/abstract: Excluded. Wrong intervention.

Eapen Z, Al-Khatib SM, Wang Y, Lopes RD, Bao H, Curtis JP, Heidenreich PA, Hernandez AF, and Hammill SC. (2011) Is cardiac resynchronization therapy use improving among racial/ethnic minorities? An analysis of 107,096 patients from the NCDR-ICD registry. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type.

Ehrlich JR, Wegener FT, Anneken L, Duray G, Israel CW, and Hohnloser SH. (2008) Biventricular pacing does not affect microvolt T-wave alternans in heart failure patients. Heart Rhythm 5:348-352. Notes: Title/abstract: Excluded. Wrong study type

Ellenbogen KA, Wood MA, and Klein HU. (2005) Why should we care about CARE-HF? Journal of the American College of Cardiology 46:2199-2203. Notes: Title/abstract: Excluded. Wrong study type.

Ellenbogen KA, Gold MR, Meyer TE, Fernandez Lozano I, Mittal S, Waggoner AD, Lemke B, Singh JP, Spinale FG, Van Eyk JE, Whitehill J, Weiner S, Bedi M, Rapkin J, and Stein KM. (2010) Primary results from the smartdelay determined AV optimization: A comparison to other AV delay methods used in cardiac resynchronization therapy (SMART-AV) trial: A randomized trial comparing empirical, echocardiography- guided, and algorithmic atrioventricular delay programming in cardiac resynchronization therapy. Circulation 122:2660-2668. Notes: Title/abstract: Excluded. Wrong intervention.

Ellenbogen KA, Gold MR, Meyer TE, Fernndez L, I, Mittal S, Waggoner AD, Lemke B, Singh JP, Spinale FG, Eyk JE, Whitehill J, Weiner S, Bedi M, Rapkin J, and Stein KM. (2010) Primary results from the SmartDelay determined AV optimization: a comparison to other AV delay methods used in cardiac resynchronization therapy (SMART-AV) trial: a randomized trial comparing empirical, echocardiography-guided, and algorithmic atrioventricular delay programming in cardiac resynchronization therapy. Circulation 122:2660-2668. Notes: Duplicate

Ellery S, Williams L, and Frenneaux M. (2006) Role of resynchronisation therapy and implantable cardioverter defibrillators in heart failure. Postgraduate Medical Journal 82:16-23. Notes: Title/abstract: Excluded. Wrong study type

Elsik M, Ring L, Duehmke R, Hutchinson J, and Virdee M. (2010) Clinical and mortality outcomes in patients undergoing CRT-P vs CRT-D device implantation in a large european tertiary centre. Heart Lung and Circulation 19:S101-S102. Notes: Title/abstract: Excluded. Wrong study type

Engelstein ED. (2003) Prevention and management of chronic heart failure with electrical therapy. American Journal of Cardiology 91:62F-73F. Notes: Title/abstract: Excluded. Wrong study type.

Epstein AE. (2005) New insights into cardiac resynchronization therapy. Clinical Cardiology 28:I45-I50. Notes: Title/abstract: Excluded. Wrong study type

Epstein AE. (2009) Update on primary prevention implantable cardioverter-defibrillator therapy. Current Cardiology Reports 11:335-342. Notes: Title/abstract: Excluded. Wrong study type.

Ermis C, Lurie KG, Zhu AX, Collins J, Vanheel L, Sakaguchi S, Lu F, Pham S, and Benditt DG. (2004) Biventricular implantable cardioverter defibrillators improve survival compared with biventricular pacing alone in patients with severe left ventricular dysfunction. Journal of Cardiovascular Electrophysiology 15:862-866. Notes: Title/abstract: Excluded. Wrong study type

Ermis C, Lurie KG, Zhu AX, Collins J, Vanheel L, Sakaguchi S, Lu F, Pham S, and Benditt DG. (2004) Biventricular implantable cardioverter defibrillators improve survival compared with biventricular pacing alone in patients with severe left ventricular dysfunction. Journal of cardiovascular. electrophysiology. 15:862-866. Notes: Duplicate

Ermis C, Seutter R, Zhu AX, Benditt LC, Vanheel L, Sakaguchi S, Lurie KG, Lu F, and Benditt DG. (2005) Impact of upgrade to cardiac resynchronization therapy on ventricular arrhythmia frequency in patients with implantable cardioverter-defibrillators. Journal of the. American. College. of Cardiology 46:2258-2263. Notes: Title/abstract: Excluded. Wrong study type

Ermis C and Benditt DG. (2006) Cardiac resynchronization pacing without defibrillator capability: Is this a viable option? Europace 8:499-501. Notes: Title/abstract: Excluded. Wrong study type

Essebag V, Birnie D, Sapp J, Sterns L, Philippon F, Yee R, Crystal E, Kus T, Rinne C, Healey J, Sami M, Thibault B, Exner D, Coutu B, Simpson C, Wulffhart Z, Wells G, and Tang AS. (2012) Incidence and predictors of upgrade to resynchronization therapy: The raft upgrade substudy. Heart Rhythm 9:S67. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Ewald GA, Gilliam FR, and Sweeney RJ. (2009) Automated HF decompensation detection: Results from the decompensation detection study (DECODE). Journal of Cardiac Failure 15:S122. Notes: Title/abstract: Excluded. Wrong study type.

Ewald GA, Gilliam FR, and Sweeney RJ. (2009) Patient risk stratification for HF decompensation. Journal of Cardiac Failure 15:S119. Notes: Title/abstract: Excluded. Wrong study type

Exner DV, Calo L, Burri H, Goodman S, Abraham W, Sumner GL, Deruvo G, Aasen-Johnston L, Biggs T, and Birnie D. (2012) Serial optimization of resynchronization device timing versus standard care - Results of the optimise CTR randomized trial. European Heart Journal 33:538. Notes: Title/abstract: Excluded. Wrong intervention.

Ezekowitz JA, Rowe BH, Dryden DM, Hooton N, Vandermeer B, Spooner C, and McAlister FA. (2007) Systematic review: implantable cardioverter defibrillators for adults with left ventricular systolic dysfunction (Structured abstract). Annals. of Internal. Medicine 147:251-262. Notes: Title/abstract: Excluded. Wrong intervention.

Faerestrand S. (2004) Cardiac resynchronisation therapy by biventricular pacing in severe heart failure. Tidsskrift for den Norske Laegeforening 124:1111-1115. Notes: Title/abstract: Excluded. Wrong study type

Fang Q, Guo T, Jackson K, and Lieberman R. (2005) Combined cardiac resynchronization and implantable cardioversion defibrillation. Zhonghua xin xue guan bing za zhi [Chinese journal of cardiovascular diseases] 33:22-25. Notes: Title/abstract: Excluded. Wrong study type

Fattore G, Priori SG, Farah G, Brown B, and Birinyi-Strachan L. (2009) Estimation of persons eligible for ICD/CRT therapy in western europe under the current ESC guidelines: A systematic review of the literature. Value in Health 12:A319. Notes: Title/abstract: Excluded. Wrong study type

Fauchier L, Poret P, Robin I, De Labriolle A, Giraudeau C, Cosnay P, and Babuty D. (2006) Different criteria of cardiac resynchronization therapy and their prognostic value for worsening heart failure or major arrhythmic events in patients with idiopathic dilated cardiomyopathy. American Journal of Cardiology 97:393-399. Notes: Title/abstract: Excluded. Wrong study type

Fazal IA, Bates MGD, Matthews IG, and Turley AJ. (2011) Do implantable cardioverter defibrillators improve survival in patients with severe left ventricular systolic dysfunction after coronary artery bypass graft surgery? Interactive Cardiovascular and Thoracic Surgery 12:1010-1016. Notes: Title/abstract: Excluded. Wrong study type.

Feingold AD and DeNofrio D. (2003) Management issues for patients with coronary artery disease and heart failure. Current Cardiology Reports 5:216-222. Notes: Title/abstract: Excluded. Wrong study type

Feldman AM, De Lissovoy G, Bristow MR, Saxon LA, De Marco T, Kass DA, Boehmer J, Singh S, Whellan DJ, Carson P, Boscoe A, Baker TM, and Gunderman MR. (2005) Cost effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial. Journal of the American College of Cardiology 46:2311-2321. Notes: Title/abstract: Excluded. Wrong study type

Feldman D, Menachemi DM, Abraham WT, and Wexler RK. (2008) Management strategies for stage-D patients with acute heart failure. Clinical Cardiology 31:297-301. Notes: Title/abstract: Excluded. Wrong study type

Fernanda Adornato EM and Adornato E. (2003) ICD therapy in heart failure. Mediterranean Journal of Pacing and Electrophysiology 5:199-202. Notes: Title/abstract: Excluded. Wrong study type

Fernandez-Armenta J, Berruezo A, Mont L, Sitges M, Andreu D, Silva E, Ortiz-Perez JT, Tolosana JM, De Caralt TM, Perea RJ, Calvo N, Trucco E, Borras R, Matas M, and Brugada J. (2012) Use of

myocardial scar characterization to predict ventricular arrhythmia in cardiac resynchronization therapy. Europace 14:1578-1586. Notes: Title/abstract: Excluded. Wrong study type.

Fernandez-Pastor J, Cabrera-Bueno F, Pena-Hernandez JL, Alzaeta-Rodriguez J, Harrera-Cordero A, Gonzalez-Gareia AB, and De Teresa-Galvan E. (2010) Electrical storm: Incidence and predictors in a series of 632 ICD recipients. Europace 12:i101. Notes: Title/abstract: Excluded. Wrong study type.

Fernandez Lozano I, Higgins S, Escudier Villa JM, Niazi I, Toquero J, Yong P, Madrid A, and Pulpon LA. (2005) Antitachycardia pacing efficacy significantly improves with cardiac resynchronization therapy. Revista Espanola de Cardiologia 58:1148-1154. Notes: Title/abstract: Excluded. Wrong intervention.

Fernández L, I, Higgins S, Escudier-Villa JM, Niazi I, Toquero J, Yong P, Madrid A, and Alonso PL. (2005) [Antitachycardia pacing efficacy significantly improves with cardiac resynchronization therapy]. Revista española. de cardiología. 58:1148-1154. Notes: Title/abstract: Excluded. Wrong intervention.

Ferreira Santos J, Parreira L, Madeira J, Fonseca N, Soares LN, and Ines L. (2003) Non Invasive Hemodinamic Monitorization for AV Interval Optimization in Patients with Ventricular Resynchronization Therapy. Revista Portuguesa de Cardiologia 22:1091-1098.
Notes: Title/abstract: Excluded. Wrong study type.

Foley PWX, Chalil S, Ratib K, Smith R, Prinzen F, Auricchio A, and Leyva F. (2011) Fluoroscopic left ventricular lead position and the long-term clinical outcome of cardiac resynchronization therapy. PACE - Pacing and Clinical Electrophysiology 34:785-797. Notes: Title/abstract: Excluded. Wrong intervention.

Fonarow GC. (2005) Strategies to improve the use of evidence-based heart failure therapies. Reviews in Cardiovascular Medicine 6:S32-S42. Notes: Title/abstract: Excluded. Wrong study type

Fonarow GC. (2006) How well are chronic heart failure patients being managed? Reviews in Cardiovascular Medicine 7:S3-S11. Notes: Title/abstract: Excluded. Wrong study type.

Fonarow GC, Yancy CW, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2008) Heart failure care in the outpatient cardiology practice setting: findings from IMPROVE HF. Circulation. Heart failure 1:98-106. Notes: Title/abstract: Excluded. Wrong study type.

Fonarow GC, Albert NM, Curtis AB, Gattis Stough W, Gheorghiade M, Heywood JT, McBride ML, Johnson Inge P, Mehra MR, O'Connor CM, Reynolds D, Walsh MN, and Yancy CW. (2010) Improving evidence-based care for heart failure in outpatient cardiology practices: Primary results of the registry to improve the use of evidence-based heart failure therapies in the outpatient setting (IMPROVE HF). Circulation 122:585-596. Notes: Title/abstract: Excluded. Wrong study type.

Fonarow GC, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, Inge PJ, Mehra MR, O'Connor CM, Reynolds D, Walsh MN, and Yancy CW. (2010) Improving evidence-based care for heart failure in outpatient cardiology practices: primary results of the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF). Circulation 122:585-596. Notes: Duplicate

Foster E, Solomon SD, McNitt S, Heintze J, Vogt J, Almendral J, Lemke B, Kloppe A, Goldenberg I, and Moss AJ. (2010) MADIT CRT: Who are the super responders to cardiac resynchronisation therapy? Europace 12:i50. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Foster E, Solomon SD, McNitt S, Goldenberg I, and Moss AJ. (2010) MADIT-CRT: Who are the super-responders to cardiac resynchronization therapy? Heart Rhythm 7:S449-S450. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: Systematic

review and economic model. Health Technology Assessment 11:iii-135. Notes: Title/abstract: Excluded. Wrong indication.

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model. Health technology assessment (Winchester, England) 11:iii-248. Notes: Duplicate

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model (Structured abstract). Health Technology Assessment. 11:1-248. Notes: Duplicate

Francia P, Salvati A, Balla C, De Paolis P, Pagannone E, Borro M, Gentile G, Simmaco M, De Biase L, and Volpe M. (2007) Cardiac resynchronization therapy increases plasma levels of the endogenous inotrope apelin. European Journal of Heart Failure 9:306-309. Notes: Title/abstract: Excluded. Wrong study type.

Freedman RA, Petrakian A, Boyce K, Haffajee C, Val-Mejias JE, and Oza AL. (2009) Performance of dedicated versus integrated bipolar defibrillator leads with CRT-defibrillators: Results from a prospective multicenter study. PACE - Pacing and Clinical Electrophysiology 32:157-165. Notes: Title/abstract: Excluded. Wrong intervention.

Freedman RA, Petrakian A, Boyce K, Haffajee C, Val-Mejias JE, and Oza AL. (2009) Performance of dedicated versus integrated bipolar defibrillator leads with CRT-defibrillators: results from a Prospective Multicenter Study. Pacing and clinical. electrophysiology. : PACE 32:157-165. Notes: Duplicate

Freeman JV and Masoudi FA. (2013) Effectiveness of Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy in Heart Failure. Heart Failure Clinics 9:59-77. Notes: Title/abstract: Excluded. Wrong study type.

Friehling M, Chen J, Saba S, Bazaz R, Schwartzman D, Adelstein EC, Garcia E, Follansbee W, and Soman P. (2011) A prospective pilot study to evaluate the relationship between acute change in left ventricular synchrony after cardiac resynchronization therapyand patient outcome using a single-injection gated SPECT protocol. Circulation: Cardiovascular Imaging 4:532-539. Notes: Title/abstract: Excluded. Wrong study type.

Fries R and Bohm M. (2003) From unstable coronary syndrome to terminal heart failure. Update cardiology 2001/2002 - Part II. Medizinische Klinik 98:326-334. Notes: Title/abstract: Excluded. Wrong study type.

Fumagalli S, Gasparini M, Lunati M, Santini M, Landolina M, Achilli A, Tronconi F, Valsecchi S, Marchionni N, and Padeletti L. (2009) Cardiac resynchronisation therapy is effective in elderly patients. The results of the InSync registry. European Heart Journal 30:306. Notes: Title/abstract: Excluded. Wrong study type.

Fumagalli S, Valsecchi S, Boriani G, Gasparini M, Landolina M, Lunati M, Padeletti M, Tronconi F, Marchionni N, and Padeletti L. (2011) Comparison of the usefulness of cardiac resynchronization therapy in three age-groups (<65, 65-74 and (greater-than or equal to)75 years) (from the InSync/InSync ICD Italian Registry). American Journal of Cardiology 107:1510-1516. Notes: Title/abstract: Excluded. Wrong study type.

Funck RC, Blanc JJ, Mueller HH, Schade BC, Bailleul C, and Maisch B. (2006) Biventricular stimulation to prevent cardiac desynchronization: rationale, design, and endpoints of the 'Biventricular Pacing for Atrioventricular Block to Prevent Cardiac Desynchronization (BioPace)' study. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac.

pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 8:629-635. Notes: Title/abstract: Excluded. Wrong study type.

Fusco A. (2007) NYHA functional class IV patients: Cardiac Resynchronization therapy with defibrillator back up. Mediterranean Journal of Pacing and Electrophysiology 9:106-108. Notes: Title/abstract: Excluded. Wrong study type

Gabizon I, Shiyovich A, Novack V, Khalameizer V, Yosefy C, Moses SW, and Katz A. (2011) Impact of descent and stay at a dead sea resort (low altitude) on patients with systolic congestive heart failure and an implantable cardioverter defibrillator. Israel Medical Association Journal 13:402-407. Notes: Title/abstract: Excluded. Wrong study type.

Gaita F, Bocchiardo M, Porciani MC, Vivalda L, Colella A, Di Donna P, Caponi D, Bruzzone M, and Padeletti L. (2000) Should stimulation therapy for congestive heart failure be combined with defibrillation backup? American Journal of Cardiology 86:165K-168K. Notes: Title/abstract: Excluded. Wrong study type.

Galizio NO, Gonzalez JL, Davila P, Medesani L, Favaloro L, Favaloro RR, Diez M, and Perrone S. (2003) Candidates for cardiac resynchronization therapy. Differences between patients with ischemic heart disease and idiopathic dilated cardiomyopathy. Prensa Medica Argentina 90:436-444. Notes: Title/abstract: Excluded. Wrong study type.

Gari E, Toledo JC, Gibert I, and Barbe J. (1992) Nucleotide sequence of the methoxyneurosporene dehydrogenase gene from Rhodobacter sphaeroides: comparison with other bacterial carotenoid dehydrogenases. FEMS microbiology letters 72:103-108. Notes: Title/abstract: Excluded. Wrong study type

Gasparini G, Bonso A, Themistoclakis S, Giada F, and Raviele A. (2001) Low-energy internal cardioversion in patients with long-lasting atrial fibrillation refractory to external electrical cardioversion: Results and long-term follow-up. Europace 3:90-95. Notes: Title/abstract: Excluded. Wrong study type.

Gasparini M, Lunati M, Bocchiardo M, Mantica M, Gronda E, Frigerio M, Caponi D, Carboni A, Boriani G, Zanotto G, Antonio Ravazzi P, Curnis A, Puglisi A, Klersy C, Vicini I, and Cavaglia S. (2003) Cardiac resynchronization and implantable cardioverter defibrillator therapy: Preliminary results from the InSync implantable cardioverter defibrillator italian registry. PACE - Pacing and Clinical Electrophysiology 26:148-151. Notes: Title/abstract: Excluded. Wrong study type.

Gasparini M, Bocchiardo M, Lunati M, Antonio Ravazzi P, Santini M, Zardini M, Signorelli S, Passardi M, and Klersy C. (2006) Comparison of 1-year effects of left ventricular and biventricular pacing in patients with heart failure who have ventricular arrhythmias and left bundle-branch block: The Bi vs Left Ventricular Pacing: An International Pilot Evaluation on Heart Failure Patients with Ventricular Arrhythmias (BELIEVE) multicenter prospective randomized pilot study. American heart journal 152:155. Notes: Title/abstract: Excluded. Wrong intervention.

Gasparini M, Lunati M, Santini M, Tritto M, Curnis A, Bocchiardo M, Vincenti A, Pistis G, Valsecchi S, and Denaro A. (2006) Long-term survival in patients treated with cardiac resynchronization therapy: A 3-year follow-up study from the InSync/InSync ICD Italian registry. PACE - Pacing and Clinical Electrophysiology 29:S2-S10. Notes: Title/abstract: Excluded. Wrong study type.

Gasparini M and Reggli F. (2006) Delayed defibrillation testing after CRT-D implant--weighing competing risks. Journal of Cardiovascular Electrophysiology 17:457-458. Notes: Title/abstract: Excluded. Wrong study type.

Gasparini M, Auricchio A, Regoli F, Fantoni C, Kawabata M, Galimberti P, Pini D, Ceriotti C, Gronda E, Klersy C, Fratini S, and Klein HH. (2006) Four-year efficacy of cardiac resynchronization therapy on exercise tolerance and disease progression: the importance of performing atrioventricular junction

ablation in patients with atrial fibrillation. Journal of the. American. College. of Cardiology 48:734-743. Notes: Title/abstract: Excluded. Wrong intervention.

Gasparini M, Bocchiardo M, Lunati M, Ravazzi PA, Santini M, Zardini M, Signorelli S, Passardi M, and Klersy C. (2006) Comparison of 1-year effects of left ventricular and biventricular pacing in patients with heart failure who have ventricular arrhythmias and left bundle-branch block: the Bi vs Left Ventricular Pacing: an International Pilot Evaluation on Heart Failure Patients with Ventricular Arrhythmias (BELIEVE) multicenter prospective randomized pilot study. American. heart journal 152:155-157. Notes: Duplicate

Gasparini M, Menozzi C, Proclemer A, Landolina M, Iacopino S, Carboni A, Lombardo E, Regoli F, Biffi M, Burrone V, Denaro A, and Boriani G. (2009) A simplified biventricular defibrillator with fixed long detection intervals reduces implantable cardioverter defibrillator (ICD) interventions and heart failure hospitalizations in patients with non-ischaemic cardiomyopathy implanted for primary prevention: The RELEVANT Role of long dEtection window programming in patients with LEft VentriculAr dysfunction. European Heart Journal 30:2758-2767. Notes: Title/abstract: Excluded. Wrong intervention.

Gasparini M, Menozzi C, Proclemer A, Landolina M, Iacopino S, Carboni A, Lombardo E, Regoli F, Biffi M, Burrone V, Denaro A, and Boriani G. (2009) A simplified biventricular defibrillator with fixed long detection intervals reduces implantable cardioverter defibrillator (ICD) interventions and heart failure hospitalizations in patients with non-ischaemic cardiomyopathy implanted for primary prevention: the RELEVANT [Role of long dEtection window programming in patients with LEft VentriculAr dysfunction, Non-ischemic eTiology in primary prevention treated with a biventricular ICD] study. European. Heart Journal 30:2758-2767. Notes: Duplicate

Gasparini M, Anselme F, Clementy J, Santini M, Martinez-Ferrer J, De Santo T, Santi E, and Schwab JO. (2010) BIVentricular versus right ventricular antitachycardia pacing to terminate ventricular tachyarrhythmias in patients receiving cardiac resynchronization therapy: The ADVANCE CRT-D Trial. American heart journal 159:1116-1123. Notes: Title/abstract: Excluded. Wrong intervention.

Gasparini M, Anselme F, Clementy J, Santini M, Martínez FJ, Santo T, Santi E, and Schwab JO. (2010) BIVentricular versus right ventricular antitachycardia pacing to terminate ventricular tachyarrhythmias in patients receiving cardiac resynchronization therapy: the ADVANCE CRT-D Trial. American. heart journal 159:1116-1123. Notes: Duplicate

Gasparini M, Proclemer A, Arenal A, Lemke B, Wijffels M, De Sousa J, Lunati M, Okreglicki A, Schwab JO, and Santi E. (2011) Minimizing ICD therapies: The ADVANCE III trial. European Heart Journal 32:922. Notes: Title/abstract: Excluded. Wrong study type.

Geldorp IE, Vernooy K, Delhaas T, Prins MH, Crijns HJ, Prinzen FW, and Dijkman B. (2010) Beneficial effects of biventricular pacing in chronically right ventricular paced patients with mild cardiomyopathy. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 12:223-229. Notes: Title/abstract: Excluded. Wrong study type.

George J, Barsheshet A, Moss AJ, Martin D, Ouellet G, McNitt S, and Goldenberg I. (2012) Effectiveness of cardiac resynchronization therapy in diabetic patients with ischemic and nonischemic cardiomyopathy. Annals of Noninvasive Electrocardiology 17:14-21. Notes: Title/abstract: Excluded. Wrong study type.

Germano JJ, Reynolds M, Essebag V, and Josephson ME. (2006) Frequency and Causes of Implantable Cardioverter-Defibrillator Therapies: Is Device Therapy Proarrhythmic? American Journal of Cardiology 97:1255-1261. Notes: Title/abstract: Excluded. Wrong study type.

Germany R, Neisen KB, Kueffer FJ, and Naftilan AJ. (2009) Integrating device diagnostic data into a disease management care model. Heart and Lung: Journal of Acute and Critical Care 38:270. Notes: Title/abstract: Excluded. Wrong study type.

Giedrimas A, Giedrimiene D, Guertin D, White CM, Clyne CA, and Kluger J. (2008) A comparison of outcomes for patients receiving implantable cardioverter defibrillators for primary vs secondary-prevention. Connecticut Medicine 72:329-333. Notes: Title/abstract: Excluded. Wrong study type.

Gilliam III FR, Singh JP, Mullin CM, McGuire M, and Chase KJ. (2007) Prognostic value of heart rate variability footprint and standard deviation of average 5-minute intrinsic R-R intervals for mortality in cardiac resynchronization therapy patients. Journal of Electrocardiology 40:336-342. Notes: Title/abstract: Excluded. Wrong study type.

Gilliam FR, Ewald GA, and Sweeney RJ. (2009) Relationship of HF patient and device data with HF decompensation events rates. Heart Rhythm 6:S258-S259. Notes: Title/abstract: Excluded. Wrong study type.

Gillis AM, Kerr C, Philippon F, Newton G, Talajic M, Froeschl M, Froesch S, Swiggum E, Wells GA, and Tang A. (2011) Impact of CRT on hospitalizations in the resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Heart Rhythm 8:S494. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Girbau JLMI, Lemke B, Merkely B, Zhang Y, Kayser T, Averina VA, Wold ND, and Thomsen PEB. (2009) Daily maximum and median respiratory rate become elevated several weeks before HF hospitalization in patients with implantable devices. Journal of Cardiac Failure 15:S53-S54. Notes: Title/abstract: Excluded. Wrong study type.

Girolami F, Ho CY, Semsarian C, Baldi M, Will ML, Baldini K, Torricelli F, Yeates L, Cecchi F, Ackerman MJ, and Olivotto I. (2010) Clinical Features and Outcome of Hypertrophic Cardiomyopathy Associated With Triple Sarcomere Protein Gene Mutations. Journal of the American College of Cardiology 55:1444-1453. Notes: Title/abstract: Excluded. Wrong study type.

Girsky MJ, Shinbane JS, Ahmadi N, Flores F, Mao S, and Budoff MJ. (2009) Three-dimensional coronary venous imaging with computed tomographic angiography facilitates cardiac resynchronization therapy. Journal of the American College of Cardiology 53:A265. Notes: Title/abstract: Excluded. Wrong study type

Girsky MJ, Shinbane JS, Ahmadi N, Mao S, Flores F, and Budoff MJ. (2010) Prospective randomized trial of venous cardiac computed tomographic angiography for facilitation of cardiac resynchronization therapy. PACE - Pacing and Clinical Electrophysiology 33:1182-1187. Notes: Title/abstract: Excluded. Wrong intervention.

Girsky MJ, Shinbane JS, Ahmadi N, Mao S, Flores F, and Budoff MJ. (2010) Prospective randomized trial of venous cardiac computed tomographic angiography for facilitation of cardiac resynchronization therapy. Pacing and clinical. electrophysiology. : PACE 33:1182-1187. Notes: Duplicate

Glatter KA, Young JN, and McElvany MD. (2006) Implantable cardioverter-defibrillators: a new preventive medical option. Preventive cardiology 9:49-53. Notes: Title/abstract: Excluded. Wrong study type.

Goetze S, Sperzel J, Biffi M, Sathaye A, Brooke MJ, Doelger A, Schubert B, and Butter C. (2007) Clinical evaluation of two different evoked response sensing methods for automatic capture detection in the left ventricle. PACE - Pacing and Clinical Electrophysiology 30:865-873. Notes: Title/abstract: Excluded. Wrong study type.

Goetze S, Lambiase P, Schilling R, Trappe HJ, Winter S, Zhang Y, Wold N, Manola L, Kestens D, and Thompson J. (2012) Daily respiratory rate trends are significantly elevated prior to HF admissions. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Gold MR, Linde C, Abraham WT, Gardiwal A, and Daubert JC. (2011) The impact of cardiac resynchronization therapy on the incidence of ventricular arrhythmias in mild heart failure. Heart Rhythm 8:679-684. Notes: Title/abstract: Included. Full text: Included. REVERSE

Gold MR, Hedayati A, Alaeddini J, Payne JP, Bailin S, Sturdivant JJL, Pradhan S, and Oza AL. (2011) Temporal stability of defibrillation thresholds with cardiac resynchronization therapy. Heart Rhythm 8:1008-1013. Notes: Title/abstract: Excluded. Wrong study type.

Gold MR, Birgersdotter-Green U, Singh JP, Ellenbogen KA, Yu Y, Meyer TE, Seth M, and Tchou PJ. (2011) The relationship between ventricular electrical delay and left ventricular remodelling with cardiac resynchronization therapy. European Heart Journal 32:2516-2524. Notes: Title/abstract: Excluded. Wrong study type.

Gold MR, Hedayati A, Alaeddini J, Payne JP, Bailin S, Sturdivant JJ, Pradhan S, and Oza AL. (2011) Temporal stability of defibrillation thresholds with cardiac resynchronization therapy. Heart rhythm. : the. official. journal of the. Heart Rhythm. Society. 8:1008-1013. Notes: Title/abstract: Excluded. Wrong study type.

Gold MR, Birgersdotter GU, Singh JP, Ellenbogen KA, Yu Y, Meyer TE, Seth M, and Tchou PJ. (2011) The relationship between ventricular electrical delay and left ventricular remodelling with cardiac resynchronization therapy. European. Heart Journal 32:2516-2524. Notes: Duplicate

Gold MR, Linde C, Abraham WT, Gardiwal A, and Daubert JC. (2011) The impact of cardiac resynchronization therapy on the incidence of ventricular arrhythmias in mild heart failure. Heart rhythm. : the. official. journal of the. Heart Rhythm. Society. 8:679-684. Notes: Duplicate

Gold MR, Daubert JC, Abraham WT, Hudnal JH, Rogers TB, and Linde C. (2012) Implantable defibrillators improve survival in mildly symptomatic heart failure patients receiving cardiac resynchronization therapy: Analysis of the 5-year follow-up of reverse. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. REVERSE

Gold MR, Dong Y, Greer S, Giudici MC, Haffajee CI, Lowy J, and Ellenbogen KA. (2012) Acute performance of a right ventricular automatic pacing threshold algorithm for implantable defibrillators. PACE - Pacing and Clinical Electrophysiology 35:259-268. Notes: Title/abstract: Excluded. Wrong study type.

Goldberger Z and Lampert R. (2006) Implantable cardioverter-defibrillators: Expanding indications and technologies. Journal of the American Medical Association 295:809-818. Notes: Title/abstract: Excluded. Wrong intervention.

Goldenberg I and Moss AJ. (2008) Implantable Device Therapy. Progress in Cardiovascular Diseases 50:449-474. Notes: Title/abstract: Excluded. Wrong study type.

Goldenberg I, Moss AJ, McNitt S, Barsheshet A, Gray D, Andrews ML, Brown MW, Zareba W, Sze E, Solomon SD, and Pfeffer MA. (2010) Relation between renal function and response to cardiac resynchronization therapy in Multicenter Automatic Defibrillator Implantation TrialCardiac Resynchronization Therapy (MADIT-CRT). Heart Rhythm 7:1777-1782. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Goldenberg I, Moss AJ, McNitt S, Barsheshet A, Gray D, Andrews ML, Brown MW, Zareba W, Sze E, Solomon SD, and Pfeffer MA. (2010) Relation between renal function and response to cardiac resynchronization therapy in Multicenter Automatic Defibrillator Implantation Trial--Cardiac Resynchronization Therapy (MADIT-CRT). Heart rhythm. : the. official. journal of the. Heart Rhythm. Society. 7:1777-1782. Notes: Duplicate

Goldenberg I, Moss AJ, Hall WJ, Foster E, Goldberger JJ, Santucci P, Shinn T, Solomon S, Steinberg JS, Wilber D, Barsheshet A, McNitt S, Zareba W, and Klein H. (2011) Predictors of response to cardiac resynchronization therapy in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). Circulation 124:1527-1536. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Goldenberg I, Hall WJ, Beck CA, Moss AJ, Barsheshet A, McNitt S, Polonsky S, Brown MW, and Zareba W. (2011) Reduction of the risk of recurring heart failure events with cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). Journal of the American College of Cardiology 58:729-737. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Goldenberg I, Moss AJ, Hall WJ, Foster E, Goldberger JJ, Santucci P, Shinn T, Solomon S, Steinberg JS, Wilber D, Barsheshet A, McNitt S, Zareba W, and Klein H. (2011) Predictors of response to cardiac resynchronization therapy in the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT). Circulation 124:1527-1536. Notes: Duplicate

Goldenberg I, Hall WJ, Beck CA, Moss AJ, Barsheshet A, McNitt S, Polonsky S, Brown MW, and Zareba W. (2011) Reduction of the risk of recurring heart failure events with cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy). Journal of the. American. College. of Cardiology 58:729-737. Notes: Duplicate

Goldfinger JZ, Choi AD, and Adler ED. (2009) Implantable cardiac defibrillators and cardiac resynchronization therapy for heart failure in older adults. Geriatrics 64:20-29. Notes: Title/abstract: Excluded. Wrong study type.

Goldman D, Greenberg S, Epstein A, Deering T, Zhang S, and Lee K. (2011) Tachycardia therapy may not increase mortality. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Goldstein RE, Krone RJ, Haigney MC, McNitt SA, and Moss AJ. (2011) Reduction in mortality among patients with left bundle branch block treated with cardiac resynchronization therapy: Results from the MADIT-CRT trial. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Goldstein RE, Haigney MC, Krone RJ, McNitt SA, and Moss AJ. (2011) Diuretic use and the benefit of cardiac resynchronization therapy to prevent heart failure and death: Secondary analysis of data from MADIT-CRT. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Golzio PG, Anselmino M, Comoglio C, Vinci M, Rinaldi M, and Trevi GP. (2009) Biventricular pacing concomitant to on-pump heart surgery: A case series. Journal of Cardiovascular Surgery 50:801-806. Notes: Title/abstract: Excluded. Wrong study type.

Gomes C, Anjo D, Meireles A, Vieira M, Santos M, Roque C, Vieira P, Lagarto V, Reis H, and Torres S. (2011) Cardiac resynchronization therapy: Is there background to use age as a criterion? European Journal of Heart Failure, Supplement 10:S256. Notes: Title/abstract: Excluded. Wrong study type.

Gorcsan J, Zareba W, Pouleur AC, Knappe D, Kutyifa V, Moss AJ, and Solomon SD. (2012) Baseline radial dyssynchrony by speckle tracking echocardiography is associated with favorable clinical outcomes after cardiac resynchronization therapy: Analysis from the MADIT-CRT trial. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Gradaus R and Breithardt G. (2007) Should all patients with heart failure and left ventricular dysfunction receive combined CRT-ICD therapy? Commentary. Nature Clinical Practice Cardiovascular Medicine 4:68-69. Notes: Title/abstract: Excluded. Wrong study type.

Gras D, Böcker D, Lunati M, Wellens HJ, Calvert M, Freemantle N, Gervais R, Kappenberger L, Tavazzi L, Erdmann E, Cleland JG, and Daubert JC. (2007) Implantation of cardiac resynchronization therapy systems in the CARE-HF trial: procedural success rate and safety. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 9:516-522. Notes: Title/abstract: Excluded. Wrong indication.

Gras D, Calo L, Isla N, Pfeiffer D, Goodma J, Guzzo L, Gupta M, and Abraha W. (2009) Baseline characteristics of patients randomized in the FREEDOM study. European Journal of Heart Failure, Supplement 8:ii274. Notes: Title/abstract: Excluded. Wrong intervention.

Gras D, Simon M, Boulogne E, and Abraham WT. (2011) Left ventricular lead adverse events observed at 1 year follow up in the multicenter randomized FREEDOM trial. European Heart Journal 32:178. Notes: Title/abstract: Excluded. Wrong intervention.

Gras D, Simon M, Boulogne E, and Abraham WT. (2011) Left ventricular lead adverse events observed at 1 year fu in the multicenter randomized freedom trial. Heart Rhythm 8:S435. Notes: Title/abstract: Excluded. Wrong intervention.

Gras D, Boulogne E, Simon M, and Abraham W. (2011) Left ventricular lead adverse events observed at 1 year FU in the FREEDOM study. Europace 13. Notes: Title/abstract: Excluded. Wrong intervention.

Greenberg S, Epstein A, Deering T, Goldman DS, Sangli C, Keeney JA, and Lee K. (2011) Impact of gender on mortality outcomes in patients receiving ICD/CRT-D therapy. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Greenberg SM, Epstein AE, Deering TF, Goldman DS, Sangli C, Keeney JA, and Lee K. (2011) Impact of gender on mortality outcomes in patients receiving ICD/CRT-D therapy. Heart Rhythm 8:S439. Notes: Title/abstract: Excluded. Wrong study type.

Gregoratos G. (2005) Indications and recommendations for pacemaker therapy. American Family Physician 71:1563-1570. Notes: Title/abstract: Excluded. Wrong study type.

Grimm W. (2008) Outcomes of elderly heart failure recipients of ICD and CRT. International Journal of Cardiology 125:154-160. Notes: Title/abstract: Excluded. Wrong study type

Guarracini F, Zuccaro LM, Rebecchi M, De Ruvo E, Sciarra L, Fagagnini A, De Luca L, Martino A, Sforza M, and Calo L. (2011) Use of the latitude patient management system for heart failure patients: A single-center prospective study. PACE - Pacing and Clinical Electrophysiology 34:1360. Notes: Title/abstract: Excluded. Wrong study type.

Guglin M and Barold SS. (2012) Electrical devices for left ventricular dysfunction and heart failure: Do we need revised guidelines? Journal of Interventional Cardiac Electrophysiology 34:197-204. Notes: Title/abstract: Excluded. Wrong study type.

Gura MT and Foreman L. (2004) Cardiac resynchronization therapy for heart failure management. AACN clinical issues 15:326-339. Notes: Title/abstract: Excluded. Wrong study type.

Habibovic M, Pedersen SS, Van Den Broek KC, Theuns DAMJ, Jordaens L, Van Der Voort PH, Alings M, and Denollet J. (2013) Anxiety and risk of ventricular arrhythmias or mortality in patients with an implantable cardioverter defibrillator. Psychosomatic Medicine 75:36-41. Notes: Title/abstract: Excluded. Wrong study type.

Haddad M, Lam K, Hendry P, Mesana T, and Davies R. (2005) Left ventricular assist devices for the treamtent of congestive heart failure. Current Treatment Options in Cardiovascular Medicine 7:47-54. Notes: Title/abstract: Excluded. Wrong study type.

Hadjis TA, Coutu B, Yee R, and Essebag V. (2011) Left ventricular capture management study. Canadian Journal of Cardiology 27:S297. Notes: Title/abstract: Excluded. Wrong study type.

Haiyan W, Yusheng X, Qiangsun Z, Yin L, Yanling T, Yi W, Luxing Z, Zhixin J, and Jianbo H. (2009) A portable, economic drainage device to prevent pocket hematoma of pacemakers. Journal of Medical Colleges of PLA 24:167-175. Notes: Title/abstract: Excluded. Wrong study type.

Haiyan W, Yusheng X, Qiangsun Z, Yin L, Yanling T, Yi W, Luxing Z, Zhixin J, and Jianbo H. (2009) A portable, economic drainage device to prevent pocket hematoma of pacemakers. Journal of Medical. Colleges. of PLA. 24:167-175. Notes: Duplicate

Hammill SC and Cain ME. (2004) Alternate training track for ICD and CRT implantation for non-electrophysiologists: Are the guidelines too strict to be practical or too simple to protect patient care? Heart Rhythm 1:376-377. Notes: Title/abstract: Excluded. Wrong study type

Handoko ML, De Man FS, Allaart CP, Paulus WJ, Westerhof N, and Vonk-Noordegraaf A. (2010) Perspectives on novel therapeutic strategies for right heart failure in pulmonary arterial hypertension: Lessons from the left heart. European Respiratory Review 19:72-82. Notes: Title/abstract: Excluded. Wrong study type

Hanna IR, Patel AD, Helmy T, and Wenger NK. (2005) Approaching cardiac arrhythmias in the elderly patient. MedGenMed Medscape General Medicine 7. Notes: Title/abstract: Excluded. Wrong study type.

Hasan A and Sun B. (2011) Defibrillators and Cardiac Resynchronization Therapy as a Bridge to Cardiac Transplantation. Heart Failure Clinics 7:227-239. Notes: Title/abstract: Excluded. Wrong study type.

Hasan A and Paul V. (2011) Telemonitoring in chronic heart failure. European Heart Journal 32:1457-1464. Notes: Title/abstract: Excluded. Wrong study type.

Hatlestad J, Mehta S, Whelan-Schwartz J, Shankar R, and Boehmer JP. (2012) Night-time elevation angles in multisense study are related to symptoms of orthopnea & paroxysmal nocturnal dyspnea. Journal of Cardiac Failure 18:S8. Notes: Title/abstract: Excluded. Wrong study type.

Hauck M, Bauer A, Voss F, Weretka S, Katus HA, and Becker R. (2009) "Home monitoring" for early detection of implantable cardioverter-defibrillator failure: A single-center prospective observational study. Clinical Research in Cardiology 98:19-24. Notes: Title/abstract: Excluded. Wrong study type.

Hauptman PJ. (2010) Device therapy in advanced heart failure: Difficult decisions, difficult discussions. Journal of Cardiac Failure 16:S131. Notes: Title/abstract: Excluded. Wrong study type.

Hauser R, Cannom D, Vlay S, Hayes D, Kallinen L, Song S, and Epstein A. (2010) ICD pulse generator longevity: A prospective multicenter study. Journal of Interventional Cardiac Electrophysiology 27:186. Notes: Title/abstract: Excluded. Wrong study type.

Hauser RG, Hayes DL, Epstein AE, Cannom DS, Vlay SC, Song SL, and Tyers GFO. (2006) Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators. Heart Rhythm 3:640-644. Notes: Title/abstract: Excluded. Wrong study type.

Hayden A, Carlson D, Webb M, Jones K, Johnson TH, Bank AJ, and Kubo SH. (2009) Impact of nurse practitioners on implementation of evidence-based therapy: Results of the St. Paul Heart Clinic heart failure database. Journal of the American College of Cardiology 53:A395. Notes: Title/abstract: Excluded. Wrong study type.

Healey J, Hohnloser SH, Exner DV, Birnie DH, Simpson CS, Sivakumaran S, Yee R, Basta M, Talajic M, Connolly SJ, Wells GA, and Tang AS. (2012) Effect of cardiac resynchronization on the development of atrial fibrillation: A report from the resynchronization for ambulatory heart failure trial (RAFT). Heart Rhythm 9:S371. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Healey JS, Hohnloser SH, Glikson M, Neuzner J, Kautzner J, Gadler F, Mabo P, Vinolas X, Van Erven L, Appl U, Gilkerson J, and Connolly SJ. (2009) A novel design for a randomized trial to test if icd implantation without any defibrillation testing is as effective as standard treatment. Heart Rhythm 6:S374-S375. Notes: Title/abstract: Excluded. Wrong study type.

Healey JS, Hohnloser SH, Exner DV, Birnie DH, Philippon F, Basta M, Yee R, Connolly SJ, Talajic M, Sivakumaran S, Yetisir E, Wells GA, and Tang AS. (2011) Does cardiac resynchronization therapy improve outcomes in patients with chronic atrial tachyarrhythmias? Results from the resynchronization for ambulatory heart failure trial (RAFT). Canadian Journal of Cardiology 27:S334-S335. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Healey JS, Hohnloser SH, Birnie DH, Exner DV, Yee R, Philippon F, Talajic M, Basta M, Sivakumaran S, Wells GA, Connolly SJ, and Tang AS. (2011) Does cardiac resynchronization therapy improve outcomes in patients with chronic atrial tachyarrhythmias? Results from the resynchronization for ambulatory heart failure trial (RAFT). Canadian Journal of Cardiology 27:S245. Notes: Duplicate.

Healey JS, Gula LJ, Birnie DH, Sterns LD, Sapp J, Crystal E, Simpson C, Exner DV, Thibault B, Philippon F, Wells GA, and Tang ASL. (2011) A randomized-controlled pilot study comparing icd implantation with and without intra-operative defibrillation testing in patients with heart failure and severe left ventricular dysfunction: A sub-study of the raft trial. Heart Rhythm 8:S499-S500. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Healey JS, Hohnloser SH, Exner DV, Birnie DH, Parkash R, Connolly SJ, Krahn AD, Simpson CS, Thibault B, Basta M, Philippon F, Dorian P, Nair GM, Sivakumaran S, Yetisir E, Wells GA, and Tang ASL. (2012) Cardiac resynchronization therapy in patients with permanent atrial fibrillation: Results from the Resynchronization for Ambulatory Heart Failure Trial (RAFT). Circulation: Heart Failure 5:566-570. Notes: Title/abstract: Included. Full text: Included. RAFT.

Healey JS, Gula LJ, Birnie DH, Sterns L, Connolly SJ, Sapp J, Crystal E, Simpson C, Exner DV, Kus T, Philippon F, Wells G, and Tang AS. (2012) A randomized-controlled pilot study comparing ICD implantation with and without intraoperative defibrillation testing in patients with heart failure and severe left ventricular dysfunction: A substudy of the RAFT trial. Journal of Cardiovascular Electrophysiology 23:1313-1316. Notes: Title/abstract: Included. Full text: Included. RAFT

Hedrich O, Weinstock J, Link M, Homoud M, and Estes III M. (2005) Device trials in heart failure: A focused summary. Reviews in Cardiovascular Medicine 6:S21-S31. Notes: Title/abstract: Excluded. Wrong study type.

Heintze J, Schloss E, Auricchio A, Zeng C, and Sterns L. (2011) Safety and performance of novel ventricular sensing discrimination features in implantable cardioverter defibrillators. Journal of the American College of Cardiology 57:E177. Notes: Title/abstract: Excluded. Wrong study type.

Heintze J, Schloss E, Auricchio A, Zeng C, and Sterns L. (2011) No compromise in VT/VF detection with novel tachyarrhythmia discrimination features in implantable cardioverter defibrillators. Europace 13:i81. Notes: Title/abstract: Excluded. Wrong study type.

Heist EK and Ruskin JN. (2006) Atrial fibrillation and congestive heart failure: Risk factors, mechanisms, and treatment. Progress in Cardiovascular Diseases 48:256-269. Notes: Title/abstract: Excluded. Wrong study type.

Heist EK, Herre JM, Binkley PF, Van Bakel AB, Porterfield JG, Porterfield LM, and Pavri BB. (2011) Analysis of a different device-based intrathoracic impedance vector for detection of heart failure events: Results Of The DEFEAT-PE study. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type.

Henyan NN, White CM, Gillespie EL, Smith K, Coleman CI, and Kluger J. (2006) The impact of gender on survival amongst patients with implantable cardioverter defibrillators for primary prevention

against sudden cardiac death. Journal of Internal Medicine 260:467-473. Notes: Title/abstract: Excluded. Wrong intervention.

Heran BS, Chen-Jenny MH, Ebrahim S, Moxham T, Oldridge N, Rees K, Thompson DR, and Taylor RS. (2011) Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Hernandez Madrid A, Escobar Cervantes C, Blanco Tirado B, Marin Marin I, Moya Mur JL, and Moro C. (2004) Cardiac resynchronization for heart failure: Background, methods, indications and results. Revista Espanola de Cardiologia 57:680-693. Notes: Title/abstract: Excluded. Wrong study type.

Herz ND, Strauss DG, Ritchey ME, Lorin Z, Jacobs SB, Silverma H, Worrall CM, Kelma J, Pina IL, and Canos DA. (2012) Cardiac resynchronization therapy defibrillators: PRE and postmarket experience. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Heywood JT, Fonarow GC, Yancy CW, Albert NM, Curtis AB, Gattis Stough W, Gheorghiade M, McBride ML, Mehra M, O'Connor C, Reynolds D, and Walsh MN. (2009) Prevalence and characteristics of prolonged qrs duration in outpatients with left ventricular systolic dysfunction: An IMPROVE HF analysis. Journal of Cardiac Failure 15:S64-S65. Notes: Title/abstract: Excluded. Wrong study type.

Heywood JT, Fonarow GC, Yancy CW, Albert NM, Curtis AB, Gattis-Stough W, Gheorghiade M, McBride ML, Mehra M, O'Connor C, Reynolds D, and Walsh MN. (2009) Influence of renal function on the use of guideline recommended heart failure therapies. Journal of the American College of Cardiology 53:A369. Notes: Title/abstract: Excluded. Wrong study type.

Heywood JT, Fonarow GC, Yancy CW, Albert NM, Curtis AB, Gheorghiade M, Inge PJ, McBride ML, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2010) Comparison of medical therapy dosing in outpatients cared for in cardiology practices with heart failure and reduced ejection fraction with and without device therapy report from IMPROVE HF. Circulation: Heart Failure 3:596-605. Notes: Title/abstract: Excluded. Wrong study type.

Hidalgo R, Martí-Carvajal AJ, Kwong-Joey SW, Simancas RD, and Nicola S. (2012) Pharmacological interventions for treating heart failure in patients with Chagas cardiomyopathy. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong indication.

Higgins SL, Yong P, Scheck D, McDaniel M, Bollinger F, Vadecha M, Desai S, and Meyer DB. (2000) Biventricular pacing diminishes the need for implantable cardioverter defibrillator therapy. Journal of the American College of Cardiology 36:824-827. Notes: Title/abstract: Excluded. Wrong intervention.

Higgins SL, Yong P, Sheck D, McDaniel M, Bollinger F, Vadecha M, Desai S, and Meyer DB. (2000) Biventricular pacing diminishes the need for implantable cardioverter defibrillator therapy. Ventak CHF Investigators. Journal of the. American. College. of Cardiology 36:824-827. Notes: Duplicate

Higgins SL, Hummel JD, Niazi IK, Giudici MC, Worley SJ, Saxon LA, Boehmer JP, Higginbotham MB, De Marco T, Foster E, and Yong PG. (2003) Cardiac Resynchronization Therapy for the Treatment of Heart Failure in Patients with Intraventricular Conduction Delay and Malignant Ventricular Tachyarrhythmias. Journal of the American College of Cardiology 42:1454-1459. Notes: Title/abstract: Included. Full text: Included. CONTAK

Higgins SL, Hummel JD, Niazi IK, Giudici MC, Worley SJ, Saxon LA, Boehmer JP, Higginbotham MB, Marco T, Foster E, and Yong PG. (2003) Cardiac resynchronization therapy for the treatment of heart failure in patients with intraventricular conduction delay and malignant ventricular tachyarrhythmias. Journal of the. American. College. of Cardiology 42:1454-1459. Notes: Duplicate

Hojgaard MV, Van Erven L, Vogt J, Kobe J, Lemke B, Kayser T, and Thomsen PEB. (2010) Is defibrillation threshold testing of high-energy ICDs necessary? Europace 12:i91. Notes: Title/abstract: Excluded. Wrong study type.

Holzmeister J and Abraham WT. (2010) Device therapy: Indications for ICD-CRT in mildly symptomatic heart failure. Nature Reviews Cardiology 7:7-8. Notes: Title/abstract: Excluded. Wrong study type.

Holzmeister J and Leclercq C. (2011) Implantable cardioverter defibrillators and cardiac resynchronisation therapy. The Lancet 378:722-730. Notes: Title/abstract: Excluded. Wrong study type.

Horlbeck FW, Mellert F, Kreuz J, Nickenig G, and Schwab JO. (2012) Real-world data on the lifespan of implantable cardioverter-defibrillators depending on manufacturers and the amount of ventricular pacing. Journal of Cardiovascular Electrophysiology 23:1336-1342. Notes: Title/abstract: Excluded. Wrong study type.

Hou W, Rosenberg SP, Koh S, Poore JW, Snell JD, Yang M, Dalal N, and Bornzin GA. (2011) Non-invasive hemodynamic assessment using photoplethysmography (PPG) for CRT optimization. Journal of Cardiac Failure 17:S12. Notes: Title/abstract: Excluded. Wrong study type

Hou W, Rosenberg S, Koh S, Poore J, Snell J, Yang M, Nirav D, and Bornzin G. (2011) Non-invasive hemodynamic assessment using photoplethysmography (PPG) for CRT optimization. Europace 13. Notes: Title/abstract: Excluded. Wrong study type

Howlett JG, Ezekowitz JA, Podder M, Hernandez AF, Diaz R, Dickstein K, Armstrong PW, and Fonarow GC. (2012) Variation in quality of care among patients hospitalized with acute heart failure in an international trial: Findings from ASCEND-HF. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Howlett JG, Ezekowitz JA, Podder M, Hernandez AF, Diaz R, Dickstein K, Arsmtrong PW, and Fonarow G. (2012) Variation in quality of care among patients hospitalized with acute heart failure in an international trial: Findings from ascend-HF. Canadian Journal of Cardiology 28:S344. Notes: Title/abstract: Excluded. Wrong study type.

Hradec J. (2004) Heart failure - Epidemy of the 21st century. Vnitrni Lekarstvi 50:S23-S31. Notes: Title/abstract: Excluded. Wrong study type.

Hsu JC, Solomon SD, Bourgoun M, McNitt S, Goldenberg I, Klein H, Moss AJ, and Foster E. (2012) Predictors of super-response to cardiac resynchronization therapy and associated improvement in clinical outcome: The MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) study. Journal of the American College of Cardiology 59:2366-2373. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Huang Y, Wu W, Cao Y, and Qu N. (2010) All cause mortality of cardiac resynchronization therapy with implantable cardioverter defibrillator: A meta-analysis of randomized controlled trials. International Journal of Cardiology 145:413-417. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Huang Y, Wu W, Cao Y, and Qu N. (2010) All cause mortality of cardiac resynchronization therapy with implantable cardioverter defibrillator: a meta-analysis of randomized controlled trials (Structured abstract). International. Journal of Cardiology 145:413-417. Notes: Duplicate

Hudson CJ, Woo GW, Miles WM, Burkart TA, Conti JB, and Schofield R. (2010) Applicability of primary prevention therapy within the veterans administration. Journal of Cardiac Failure 16:S105. Notes: Title/abstract: Excluded. Wrong study type.

Inglis SC, Clark RA, McAlister FA, Ball J, Lewinter C, Cullington D, Stewart S, and Cleland-John GF. (2010) Structured telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Ip J, Waldo AL, Lip GYH, Rothwell PM, Martin DT, Bersohn MM, Choucair WK, Akar JG, Wathen MS, Rohani P, and Halperin JL. (2009) Multicenter randomized study of anticoagulation guided by remote

rhythm monitoring in patients with implantable cardioverter-defibrillator and CRT-D devices: Rationale, design, and clinical characteristics of the initially enrolled cohort. The IMPACT study. American heart journal 158:364-370. Notes: Title/abstract: Excluded. Wrong intervention.

Ip J, Waldo AL, Lip GY, Rothwell PM, Martin DT, Bersohn MM, Choucair WK, Akar JG, Wathen MS, Rohani P, and Halperin JL. (2009) Multicenter randomized study of anticoagulation guided by remote rhythm monitoring in patients with implantable cardioverter-defibrillator and CRT-D devices: Rationale, design, and clinical characteristics of the initially enrolled cohort The IMPACT study. American. heart journal 158:364-370. Notes: Duplicate

Israel CW. (2004) Pacing in the prevention and termination of atrial tachyarrhythmias. Herzschrittmachertherapie und Elektrophysiologie 15:147-164. Notes: Title/abstract: Excluded. Wrong study type.

Israel CW and Butter C. (2006) Indication for cardiac resynchronization therapy: Consensus 2005. Herzschrittmachertherapie und Elektrophysiologie 17:I/80-I/86. Notes: Title/abstract: Excluded. Wrong study type.

Israel CW. (2008) Sandwiched between the single- and triple-chamber ICD: Do we still need the dual-chamber ICD? Herzschrittmachertherapie und Elektrophysiologie 19:14-24. Notes: Title/abstract: Excluded. Wrong study type.

Israel CW. (2011) Electrical therapy for heart failure. Perspectives for 2011. Herzschrittmachertherapie und Elektrophysiologie 22:34-38. Notes: Title/abstract: Excluded. Wrong study type.

Israel CW, Anker SD, and Hasenfuss G. (2012) Commentary on the 2010 ESC guidelines on device therapy in heart failure. Kardiologe 6:5-11. Notes: Title/abstract: Excluded. Wrong study type.

Israel CW, Anker SD, and Hasenfuss G. (2012) Commentary on the 2010 ESC guidelines on device therapy in heart failure. Herzschrittmachertherapie und Elektrophysiologie 23:33-37. Notes: Title/abstract: Excluded. Wrong study type.

Jame S, Tanabe K, Bhamre S, Polonsky S, McNitt S, Moss AJ, Zareba W, Al-Ahmad A, and Wang PJ. (2012) Baseline heart rate variability predicts ventricular tachyarrhythmia occurrence. Heart Rhythm 9:S106. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Jamerson D, Tompkins C, McNitt S, Polonsky B, Zareba W, and Moss A. (2012) Early procedure-related adverse events by gender in MADIT-CRT. Journal of the American College of Cardiology 59:E919. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Jankowska, Kurian B, Zajaczkowski C, Banasiak W, and Ponikowski P. (2011) ESC guidelines implementation in the management of outpatients with systolic heart failure by cardiologists and general practitioners in Poland. European Journal of Heart Failure, Supplement 10:S236. Notes: Title/abstract: Excluded. Wrong study type.

Jankowska EA, Zajaczkowski C, Bentkowski Z, Banasiak W, and Ponikowski P. (2011) Differences between diabetic and non-diabetic outpatients with systolic heart failure in the implementation of European guidelines in Poland. European Journal of Heart Failure, Supplement 10:S132. Notes: Title/abstract: Excluded. Wrong study type.

Jankowska EA, Kurian B, Zajaczkowski C, Banasiak W, and Ponikowski P. (2011) Management of patients with systolic heart failure by cardiologists versus general practitioners in Poland: Do we implement ESC guidelines efficiently? European Heart Journal 32:919. Notes: Title/abstract: Excluded. Wrong study type

Jeevanantham V, Zareba W, Navaneethan S, Fitzgerald D, Yu CM, Achilli A, Bax J, and Daubert J. (2008) Metaanalysis on effects of cardiac resynchronization therapy in heart failure patients with

narrow QRS complex (Structured abstract). Cardiology Journal 15:230-236. Notes: Title/abstract: Excluded. Wrong indication.

Jego C and Deharo JC. (2004) Implantable defibrillator and ventricular resynchronisation. Archives des Maladies du Coeur et des Vaisseaux 97:1122-1129. Notes: Title/abstract: Excluded. Wrong study type.

Jensen SB, Galvin CA, Thompson B, and Rasmussen MJ. (2007) Optimizing therapy for heart failure patients: cardiac resynchronization and defibrillator therapy. The Journal of cardiovascular nursing 22:118-124. Notes: Title/abstract: Excluded. Wrong study type

Jessup M. (2003) Resynchronization therapy is an important advance in the management of congestive heart failure: View of an antagonist. Journal of Cardiovascular Electrophysiology 14:S30-S34. Notes: Title/abstract: Excluded. Wrong study type.

Ji SY and Travin MI. (2010) Radionuclide imaging of cardiac autonomic innervation. Journal of Nuclear Cardiology 17:655-666. Notes: Title/abstract: Excluded. Wrong study type

Ji SY, Gundewar S, and Palma EC. (2012) Subclavian venoplasty may reduce implant times and implant failures in the era of increasing device upgrades. PACE - Pacing and Clinical Electrophysiology 35:444-448. Notes: Title/abstract: Excluded. Wrong study type.

Jiang M, He B, and Zhang Q. (2012) Comparison of CRT and CRT-D in heart failure: Systematic review of controlled trials. International Journal of Cardiology 158:39-45. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Jiang M, He B, and Zhang Q. (2012) Comparison of CRT and CRT-D in heart failure: systematic review of controlled trials (Structured abstract). International. Journal of Cardiology 158:39-45. Notes: Duplicate

John-Sutton MG, Plappert T, Abraham WT, Smith AL, DeLurgio DB, Leon AR, Loh E, Kocovic DZ, Fisher WG, Ellestad M, Messenger J, Kruger K, Hilpisch KE, and Hill MR. (2003) Effect of cardiac resynchronization therapy on left ventricular size and function in chronic heart failure. Circulation 107:1985-1990. Notes: Title/abstract: Excluded. Wrong intervention.

John Camm A and Nisam S. (2010) European utilization of the implantable defibrillator: Has 10 years changed the enigma? Europace 12:1063-1069. Notes: Title/abstract: Excluded. Wrong study type.

John Sutton MG, Ghio S, Plappert T, Tavazzi L, Scelsi L, Daubert C, Abraham WT, Gold MR, Hassager C, Herre JM, Derumeaux G, and Linde C. (2009) Cardiac resynchronization therapy induces major structural and functional reverse remodeling in mild heart failure. Results from the resynchronization reverses remodeling in systolic left ventricular dysfunction (REVERSE) trial. Journal of the American College of Cardiology 53:A187. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract.

John SM. (2009) Cardiac resynchronization therapy and reduced risk of death and nonfatal heart failure events. Current. heart failure. reports. 6:211-212. Notes: Title/abstract: Excluded. Wrong study type.

Jons C and Thomsen PEB. (2012) Treating cardiac arrhythmias detected with an implantable cardiac monitor in patients after an acute myocardial infarction. Current Treatment Options in Cardiovascular Medicine 14:39-49. Notes: Title/abstract: Excluded. Wrong study type.

Joshi SB, Blum AR, Mansour M, and Abbara S. (2009) CT Applications in Electrophysiology. Cardiology Clinics 27:619-631. Notes: Title/abstract: Excluded. Wrong study type.

Juilliere Y. (2003) The best of cardiac failure in 2002. Archives des Maladies du Coeur et des Vaisseaux 96:15-18. Notes: Title/abstract: Excluded. Wrong study type.

Jung W and Luderitz B. (1998) Implantable atrial defibrillator. Herz 23:251-259. Notes: Title/abstract: Excluded. Wrong study type.

Jung W, Wolpert C, Herwig S, Spehl S, Esmailzadeh B, Schneider C, Schumacher B, Lewalter T, Schimpf R, Omran H, Kirchhoff PG, and Luderitz B. (1998) Initial experience with the implantable atrial and combined atrioventricular defibrillator. Herzschrittmachertherapie und Elektrophysiologie 9:94-101. Notes: Title/abstract: Excluded. Wrong study type.

Jung W, Wolpert C, Esmailzadeh B, Spehl S, Herwig S, Schumacher B, Lewalter T, Omran H, Kirchhoff PG, and Luderitz B. (1998) Specific considerations with the automatic implantable atrial defibrillator. Journal of Cardiovascular Electrophysiology 9:S193-S201. Notes: Title/abstract: Excluded. Wrong study type

Jung W, Schumacher B, Lewalter T, and Luderitz B. (1998) Incidence of atrial fibrillation: Implications for device therapy. Cor Europaeum - European Journal of Cardiac Interventions 7:78-80. Notes: Title/abstract: Excluded. Wrong study type.

Jung W and Luderitz B. (2000) Implantable atrial defibrillator. Zeitschrift fur Kardiologie 89:III206-III214. Notes: Title/abstract: Excluded. Wrong study type.

Kadish AH, Reiffel JA, Naccarelli GV, and Dimarco JP. (2008) Device Therapies in the Post-Myocardial Infarction Patient with Left Ventricular Dysfunction. American Journal of Cardiology 102:29G-37G. Notes: Title/abstract: Excluded. Wrong study type.

Kalahasty G, Shepard RK, Lobban JH, Giudici MC, Doshi RN, Gallagher P, Dong Y, McCabe AR, Shome S, Gold MR, and Ellenbogen KA. (2010) Acute clinical performance of a new left ventricular autothreshold algorithm. Heart Rhythm 7:S303. Notes: Title/abstract: Excluded. Wrong study type.

Kalahasty G, Shepard RK, Lobban JH, Giudici MC, Doshi RN, Gallagher P, Dong Y, McCabe AR, Shome S, Gold MR, and Ellenbogen KA. (2010) Acute capture detection performance of a new left ventricular autothreshold algorithm. Heart Rhythm 7:S431-S432. Notes: Title/abstract: Excluded. Wrong study type.

Kalahasty G, Giudici M, Lobban J, Doshi R, Delaney C, Shome S, Gold MR, and Ellenbogen K. (2012) Acute clinical evaluation of a left ventricular automatic threshold determination algorithm based on evoked response sensing. PACE - Pacing and Clinical Electrophysiology 35:348-356. Notes: Title/abstract: Excluded. Wrong study type.

Kalinchak DM and Schoenfeld MH. (2003) Cardiac Resynchronization: A Brief Synopsis Part I: Patient Selection and Results from Clinical Trials. Journal of Interventional Cardiac Electrophysiology 9:155-161. Notes: Title/abstract: Excluded. Wrong study type.

Kallinen LM and Hauser R. (2009) Longevity of ICD pulse generators: 10-year multicenter experience. European Heart Journal 30:308-309. Notes: Title/abstract: Excluded. Wrong study type.

Kang S and Cannom DS. (2004) Current role of device therapy to reduce sudden cardiac death in heart failure. Current heart failure reports 1:104-110. Notes: Title/abstract: Excluded. Wrong study type.

Kaprielian R and Lefroy DC. (2003) Biventricular pacing in heart failure: Current status and future horizons. Continuing Medical Education - Cardiology 2:177-184. Notes: Title/abstract: Excluded. Wrong study type

Kartal Y, Yavuzgil O, Bozoglu M, Alp A, Can LH, and Hasdemir C. (2012) Cardiac resynchronization therapy with or without anatomical reverse remodeling does not affect defibrillation threshold. PACE - Pacing and Clinical Electrophysiology 35:416-421. Notes: Title/abstract: Excluded. Wrong study type.

Kashani A and Barold SS. (2005) Significance of QRS complex duration in patients with heart failure. Journal of the American College of Cardiology 46:2183-2192. Notes: Title/abstract: Excluded. Wrong study type.

Kaufmann BA, Min SY, Goetschalckx K, Bernheim AM, Buser PT, Pfisterer ME, and Brunner-La Rocca HP. (2012) How reliable are left ventricular ejection fraction cut offs assessed by echocardiography for clinical decision making in patients with heart failure? International Journal of Cardiovascular Imaging1-8. Notes: Title/abstract: Excluded. Wrong study type.

Kautzner J and Riedlbauchova L. (2003) Biventricular heart pacing. Vnitrni Lekarstvi 49:734-739. Notes: Title/abstract: Excluded. Wrong study type.

Kawakami T and Ichinose H. (2004) Double target method (double marker-guided extrathoracic introducer insertion). PACE - Pacing and Clinical Electrophysiology 27:818-820. Notes: Title/abstract: Excluded. Wrong study type.

Kazi DS and Mark DB. (2013) The Economics of Heart Failure. Heart Failure Clinics 9:93-106. Notes: Title/abstract: Excluded. Wrong study type.

Kedia R and Saeed M. (2012) Implantable cardioverter-defibrillators: Indications and unresolved issues. Texas Heart Institute Journal 39:335-341. Notes: Title/abstract: Excluded. Wrong study type.

Kettering K, Mewis C, Riemer M, and Kuhlkamp V. (2000) Ventricular fibrillation resulting from synchronized intra-atrial defibrillation. Zeitschrift fur Kardiologie 89:269-273. Notes: Title/abstract: Excluded. Wrong study type

Kidwai BJ, McIntyre A, Anderson J, and Adgey AAJ. (2002) Optimization of transthoracic ventricular defibrillation-biphasic and triphasic shocks, waveform rounding, and synchronized shock delivery. Journal of Electrocardiology 35:235-244. Notes: Title/abstract: Excluded. Wrong study type

Kiesewetter C, Michael K, Morgan J, and Veldtman GR. (2008) Left ventricular dysfunction after cardiac resynchronization therapy in congenital heart disease patients with a failing systemic right ventricle. PACE - Pacing and Clinical Electrophysiology 31:159-162. Notes: Title/abstract: Excluded. Wrong study type.

Killu AM, Wu JH, Friedman PA, Shen WK, Webster TL, Brooke KL, Hodge DO, Wiste HJ, and Cha YM. (2012) Outcomes of Cardiac Resynchronization Therapy in the Elderly. PACE - Pacing and Clinical Electrophysiology. Notes: Title/abstract: Excluded. Wrong study type

Klabnik A, Murin J, and Kycina P. (2010) Gender differences in non-pharmacological treatment of chronic heart failure. Vnitrni Lekarstvi 56:427-433. Notes: Title/abstract: Excluded. Wrong study type.

Kleemann T, Becker T, Strauss M, Dyck N, Schneider S, Weisse U, Saggau W, Cornelius B, Layer G, and Seidl K. (2010) Impact of left ventricular lead position on the incidence of ventricular arrhythmia and clinical outcome in patients with cardiac resynchronization therapy. Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing 28:109-116. Notes: Title/abstract: Excluded. Wrong study type.

Klein HU. (2003) Device therapy for congestive heart failure: Which devices are indicated? European Heart Journal, Supplement 5:I75-I82. Notes: Title/abstract: Excluded. Wrong study type.

Klein HU. (2004) Device therapy for congestive heart failure: Which devices are indicated? European Heart Journal, Supplement 6:I75-I82. Notes: Title/abstract: Excluded. Wrong study type.

Klein HU. (2010) Cardiac resynchronization therapy in asymptomatic or mildly symptomatic heart failure patients. Current Treatment Options in Cardiovascular Medicine 12:431-442. Notes: Title/abstract: Excluded. Wrong study type.

Klein MH and Gold MR. (2008) Use of Traditional and Biventricular Implantable Cardiac Devices for Primary and Secondary Prevention of Sudden Death. Cardiology Clinics 26:419-431. Notes: Title/abstract: Excluded. Wrong study type.

Klein N, Klein M, Weglage H, Przibille O, Fischer S, Trappe HJ, Birkenhauer F, and Pfeiffer D. (2012) Clinical efficacy of left ventricular pacing vector programmability in cardiac resynchronization therapy defibrillator patients for management of phrenic nerve stimulation and/or elevated left ventricular pacing thresholds: Insights from the Efface Phrenic Stim study. Europace 14:826-832. Notes: Title/abstract: Excluded. Wrong study type.

Kloner RA and Cannom DS. (2007) Uncertainty on the use of aldosterone antagonists for primary therapy for sudden cardiac death in the setting of implanted devices. Circulation 115:2983-2989. Notes: Title/abstract: Excluded. Wrong study type.

Kloppe A, Mijic D, Bogossian H, Ninios I, Zarse M, and Lemke B. (2011) A new combined stylet/guide wire-tool for left ventricular lead placement for cardiac resynchronisation therapy. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Knappe D, Pouleur AC, Shah AM, Cheng S, Uno H, Hall WJ, Bourgoun M, Foster E, Zareba W, Goldenberg I, McNitt S, Pfeffer MA, Moss AJ, and Solomon SD. (2011) Dyssynchrony, contractile function, and response to cardiac resynchronization therapy. Circulation: Heart Failure 4:433-440. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Knappe D, Pouleur AC, Shah AM, Cheng S, Uno H, Hall WJ, Bourgoun M, Foster E, Zareba W, Goldenberg I, McNitt S, Pfeffer MA, Moss AJ, and Solomon SD. (2011) Dyssynchrony, contractile function, and response to cardiac resynchronization therapy. Circulation. Heart failure. 4:433-440. Notes: Duplicate

Knebel F, Schattke S, Bondke H, Richter C, Melzer C, Dreger H, Grohmann A, Baumann G, and Borges AC. (2008) Implementation of seven echocardiographic parameters of myocardial asynchrony to improve the long-term response rate of cardiac resynchronization therapy (CRT). Cardiovascular ultrasound 6:58. Notes: Title/abstract: Excluded. Wrong study type.

Knight BP, Desai A, Coman J, Faddis M, and Yong P. (2004) Long-term retention of cardiac resynchronization therapy. Journal of the. American. College. of Cardiology 44:72-77. Notes: Title/abstract: Excluded. Wrong indication.

Knops P, Theuns DAMJ, Res JCJ, and Jordaens L. (2009) Analysis of implantable defibrillator longevity under clinical circumstances: Implications for device selection. PACE - Pacing and Clinical Electrophysiology 32:1276-1285. Notes: Title/abstract: Excluded. Wrong study type.

Koepp U, Gjestvang FT, Eivindson G, and Myhre ESP. (2009) Low total mortality rates due to extended use of optimal medical treatment and CRT-D in a primary prophylactic ICD population. European Journal of Heart Failure, Supplement 8:ii56. Notes: Title/abstract: Excluded. Wrong study type.

Kolb C, Solzbach U, Lemke B, Klein N, Szendey I, Tzeis S, Andrikopoulos G, Semmler V, Lennerz C, and Asbach S. (2012) Safety of ICD electrode positioning in the right ventricular mid-septum versus apex - Results from a randomised trial. European Heart Journal 33:539. Notes: Title/abstract: Excluded. Wrong intervention.

Koontz JI, Haithcock D, Cumbea V, Waldron A, Stricker K, Hughes A, Nilsson K, Sun A, Piccini JP, Kraus WE, Pitt GS, Shah SH, and Hranitzky P. (2009) Rationale and design of the Duke Electrophysiology Genetic and Genomic Studies (EPGEN) biorepository. American heart journal 158:719-725. Notes: Title/abstract: Excluded. Wrong study type.

Kopp U, Gjestvang FT, Eivindson G, and Myhre ESP. (2010) Low total mortality rates due to extended use of optimal medical treatment and CRT-D in a primary prophylactic ICD population. Europace 12:i140. Notes: Title/abstract: Excluded. Wrong study type.

Krahn AD, Snell L, Yee R, Finan J, Skanes AC, and Klein GJ. (2002) Biventricular pacing improves quality of life and exercise tolerance in patients with heart failure and intraventricular conduction delay. Canadian Journal of Cardiology 18:380-387. Notes: Title/abstract: Excluded. Wrong study type.

Krishnamani R and DeNofrio D. (2004) Device therapy for the management of advanced heart failure. Expert Review of Cardiovascular Therapy 2:573-580. Notes: Title/abstract: Excluded. Wrong study type.

Kron J, Aranda J, Miles WM, Burkart TA, Woo GW, Saxonhouse SJ, Sears J, and Conti JB. (2009) Benefit of cardiac resynchronization in elderly patients: Results from the Multicenter InSync Randomized Clinical Evaluation (MIRACLE) and Multicenter InSync ICD Randomized Clinical Evaluation (MIRACLE-ICD) trials. Journal of Interventional Cardiac Electrophysiology 25:91-96. Notes: Title/abstract: Excluded. Wrong indication.

Krum H and Abraham WT. (2009) Heart failure. The Lancet 373:941-955. Notes: Title/abstract: Excluded. Wrong study type.

Kubo SH, Hayden A, Carlson D, Webb M, Jones K, Johnson TH, and Bank AJ. (2009) Impact of nurse practitioners on implementation of evidence based therapy: Results of the St. Paul Heart Clinic (SPHC) heart failure database. Heart and Lung: Journal of Acute and Critical Care 38:275-276. Notes: Title/abstract: Excluded. Wrong study type.

Kuhlkamp V. (2002) Initial experience with an implantable cardioverter-defibrillator incorporating cardiac resynchronization therapy. Journal of the American College of Cardiology 39:790-797. Notes: Title/abstract: Excluded. Wrong study type.

Kuhlkamp V, Dornberger V, Rub N, Eigenberger B, Kettering K, Bosch R, and Mewis C. (2003) Experience with an ICD incorporating biventricular pacing. Minerva Cardioangiologica 51:209-213. Notes: Title/abstract: Excluded. Wrong study type

Kullmer M, Albanese M, and Schols W. (2009) Cardiac resynchronization therapy: Is there always a need for the adjunctive ICD therapy? Herzschrittmachertherapie und Elektrophysiologie 20:143-147. Notes: Title/abstract: Excluded. Wrong study type.

Kurita T. (2010) The present status and the future of the device therapy for patients with heart failure. Journal of Cardiac Failure 16:S132. Notes: Title/abstract: Excluded. Wrong study type.

Kusnitz J, Codner P, Haim M, and Zabarski R. (2010) Implantation of cardioverter defibrillator for primary and secondary prevention of sudden death with and without defibrillation threshold testing: 3-year follow-up. Europace 12:i90. Notes: Title/abstract: Excluded. Wrong study type.

Kusumoto F and Goldschlager N. (2005) Beyond heart rhythms: New directions for implantable devices. Journal of Interventional Cardiac Electrophysiology 14:5-7. Notes: Title/abstract: Excluded. Wrong study type.

Kusumoto FM and Goldschlager N. (2006) Implantable cardiac arrhythmia devices - Part I: Pacemakers. Clinical Cardiology 29:189-194. Notes: Title/abstract: Excluded. Wrong study type.

Kutyifa V, Zareba W, McNitt S, Singh J, Hall WJ, Polonsky S, Goldenberg I, Huang DT, Merkely B, Wang PJ, Moss AJ, and Klein H. (2013) Left ventricular lead location and the risk of ventricular arrhythmias in the MADIT-CRT trial. European Heart Journal 34:184-190. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Lalukota K, Cleland JGF, Ingle L, Clark AL, and Coletta AP. (2004) Clinical trials update from the Heart Failure Society of America: EMOTE, HERB-CHF, BEST genetic sub-study and RHYTHM-ICD. European Journal of Heart Failure 6:953-955. Notes: Title/abstract: Excluded. Wrong study type

Lam SK and Owen A. (2007) Combined resynchronisation and implantable defibrillator therapy in left ventricular dysfunction: Bayesian network meta-analysis of randomised controlled trials (Structured abstract). BMJ 335:925. Notes: Duplicate

Lam SKH and Owen A. (2007) Combined resynchronisation and implantable defibrillator therapy in left ventricular dysfunction: Bayesian network meta-analysis of randomised controlled trials. British Medical Journal 335:925-928. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail. Does not report results for NYHA class II.

Lam SKH and Owen A. (2008) What is the level of evidence for combined cardiac resynchronization and defibrillation therapy in heart failure? Europace 10:511. Notes: Title/abstract: Excluded. Wrong study type

Landolina M, Lunati M, Gasparini M, Santini M, Padeletti L, Achilli A, Bianchi S, Laurenzi F, Curnis A, Vincenti A, Valsecchi S, and Denaro A. (2007) Comparison of the Effects of Cardiac Resynchronization Therapy in Patients With Class II Versus Class III and IV Heart Failure (from the InSync/InSync ICD Italian Registry)(dagger)(dagger)Conflicts of interest: .. American Journal of Cardiology 100:1007-1012. Notes: Title/abstract: Excluded. Wrong study type.

Lau CP, Barold S, Tse HF, Lee KLF, Chan HW, Fan K, Chau E, and Yu CM. (2003) Advances in Devices for Cardiac Resynchronization in Heart Failure. Journal of Interventional Cardiac Electrophysiology 9:167-181. Notes: Title/abstract: Excluded. Wrong study type.

Lavalle C, Ricci RP, and Santini M. (2010) Atrial tachyarrhythmias and cardiac resynchronisation therapy: Clinical and therapeutic implications. Heart 96:1174-1178. Notes: Title/abstract: Excluded. Wrong study type.

Lazarus A, Biondi N, Thebaut JF, Durand-Zaleski I, and Chauvin M. (2011) Implantable cardioverter-defibrillators in France: practices and regional variability. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 13:1568-1573. Notes: Title/abstract: Excluded. Wrong study type.

Le Gloan L and Khairy P. (2011) Management of arrhythmias in patients with tetralogy of Fallot. Current Opinion in Cardiology 26:60-65. Notes: Title/abstract: Excluded. Wrong study type

Lechat P. (2006) The evolution of heart failure management over recent decades: From CONSENSUS to CIBIS. European Heart Journal, Supplement 8:C5-C12. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C and Kass DA. (2002) Retiming the failing heart: Principles and current clinical status of cardiac resynchronization. Journal of the American College of Cardiology 39:194-201. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C and Daubert JC. (2003) Cardiac resynchronization therapy is an important advance in the management of congestive heart failure. Journal of Cardiovascular Electrophysiology 14:S27-S29. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C and Hare JM. (2004) Ventricular Resynchronization: Current State of the Art. Circulation 109:296-299. Notes: Title/abstract: Excluded. Wrong study type

Leclercq C, Crocq C, Mabo P, and Daubert C. (2004) Role of cardiac resynchronisation in the treatment of cardiac failure. Archives des Maladies du Coeur et des Vaisseaux 97:1116-1121. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C. (2005) Cardiac resynchronisation therapy: What kind of equipment using? Annales de Cardiologie et d'Angeiologie 54:12-16. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C, Ansalone G, Gadler F, Boriani G, Perez-Castellano N, Grubb N, Sack S, and Boulogne E. (2006) Biventricular vs. left univentricular pacing in heart failure: Rationale, design, and endpoints of the B-LEFT HF study. Europace 8:76-80. Notes: Title/abstract: Excluded. Wrong intervention.

Leclercq C, Mabo C, and Daubert JC. (2008) Cardiac resynchronization therapy: Which device to implant? Archives of Cardiovascular Diseases 101:55-60. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq CH and Hero M. (2011) Results of the survey ITHAQUE: Monitoring and therapies for systolic heart failure. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Lee DS, Krahn AD, Healey JS, Birnie D, Crystal E, Dorian P, Simpson CS, Khaykin Y, Cameron D, Janmohamed A, Yee R, Austin PC, Chen Z, Hardy J, and Tu JV. (2010) Evaluation of Early Complications Related to De Novo Cardioverter Defibrillator Implantation. Insights From the Ontario ICD Database. Journal of the American College of Cardiology 55:774-782. Notes: Title/abstract: Excluded. Wrong study type.

Lee DS, Gula L, Mangat I, Healey JS, Yee R, Krahn AD, Simpson CS, Crystal E, Birnie D, Cameron D, Khaykin Y, Wang X, Dorian P, and Tu JV. (2011) Outcomes of primary prevention implantable cardioverter defibrillator (ICD) recipients with vs without clinical trial entry criteria: Observations from a comprehensive provincial icd registry. Canadian Journal of Cardiology 27:S294. Notes: Title/abstract: Excluded. Wrong study type

Lee MY. (2006) Cardiac resynchronization therapy; biventricular pacing. Korean Circulation Journal 36:329-336. Notes: Title/abstract: Excluded. Wrong study type.

Lefevre F. (2010) Cardiac resynchronization therapy for mild congestive heart failure (Provisional abstract). Database. of Abstracts. of Reviews. of Effects.1. Notes: Title/abstract: Excluded. Wrong study type.

Lehmann HI, Wolke C, Malenke W, Rohl FW, Hammwohner M, Bukowska A, Lendeckel U, and Goette A. (2012) Enzymatic activity of DPIV and renin-angiotensin system (RAS) proteases in patients with left ventricular dysfunction and primary prevention implantable cardioverter/defibrillator (ICD). International Journal of Cardiology. Notes: Title/abstract: Excluded. Wrong study type.

Lehmann MH and Aaronson KD. (2006) CRT-D therapy in heart failure: How much do NYHA class IV patients benefit? Journal of Cardiovascular Electrophysiology 17:491-494. Notes: Title/abstract: Excluded. Wrong study type

Lellouche N, De Diego C, Boyle NG, Wiener I, Akopyan G, Child JS, and Shivkumar K. (2011) Relationship between mechanical and electrical remodelling in patients with cardiac resynchronization implanted defibrillators. Europace 13:1180-1187. Notes: Title/abstract: Excluded. Wrong study type.

Lenarczyk R, Kowalski O, Sredniawa B, Pruszkowska-Skrzep P, Pluta S, Sokal A, Kukulski T, StabryLa-Deska J, Wozniak A, Kowalczyk J, ZieliNska T, Mazurek M, Streb W, Zembala M, and Kalarus Z. (2009) Triple-site versus standard cardiac resynchronization therapy study (TRUST CRT): Clinical rationale, design, and implementation. Journal of Cardiovascular Electrophysiology 20:658-662. Notes: Title/abstract: Excluded. Wrong indication.

Lenarczyk R, Kowalski O, Sredniawa B, Pruszkowska-Skrzep P, Pluta S, Sokal A, Szulik M, Kukulski T, ZieliNska T, and Kalarus Z. (2011) Triple-site cardiac resynchronization therapy in patients with heart failure - the prospective, randomized trial. European Heart Journal 32:145. Notes: Title/abstract: Excluded. Wrong indication.

Lenarczyk R, Kowalski O, Sredniawa B, Pruszkowska-Skrzep P, Mazurek M, Jedrzejczyk-Patej E, Wozniak A, Pluta S, Glowacki J, and Kalarus Z. (2012) Implantation feasibility, procedure-related adverse events and lead performance during 1-year follow-up in patients undergoing triple-site cardiac resynchronization therapy: A substudy of TRUST CRT randomized trial. Journal of Cardiovascular Electrophysiology 23:1228-1236. Notes: Title/abstract: Excluded. Wrong intervention.

Lenarczyk R, Kowalski O, Sredniawa B, Pruszkowska P, Mazurek M, Jedrzejczyk-Patej E, Wozniak A, and Kalarus Z. (2012) Feasibility and safety of triple-site CRT-insights from the randomized trial. European Heart Journal 33:532. Notes: Title/abstract: Excluded. Wrong intervention

Leon AR, Abraham WT, Curtis AB, Daubert JP, Fisher WG, Gurley J, Hayes DL, Lieberman R, Petersen-Stejskal S, and Wheelan K. (2005) Safety of transvenous cardiac resynchronization system implantation in patients with chronic heart failure: Combined results of over 2,000 patients from a multicenter study program. Journal of the American College of Cardiology 46:2348-2356. Notes: Title/abstract: Excluded. Wrong study type.

Lercher P, Thudt K, Linder S, Mayr H, and Pieske BM. (2009) Very positive patient feedback along with dramatic time savings in use of remote followup of icd patients. Heart Rhythm 6:S258. Notes: Title/abstract: Excluded. Wrong study type

Lercher P, Raatikainen MJP, Landolina M, Marquie C, Busca R, and Thudt K. (2009) Clinicians perspective on remote monitoring for ICD/CRT patients - A prospective study in 4 European Countries. Journal of Cardiovascular Electrophysiology 20:S63. Notes: Title/abstract: Excluded. Wrong study type

Lerner DJ, Bloom HL, Constantin L, DeLurgio DB, Hackett K, Kanuru NK, Rasekh A, and Sogade FO. (2009) AIGISRx anti-bacterial envelope retrospective registry results - Report of first analyses. American Journal of Cardiology 104:195D-196D. Notes: Title/abstract: Excluded. Wrong study type.

Lévy S, Ricard P, Gueunoun M, Yapo F, Trigano J, Mansouri C, and Paganelli F. (1997) Low-energy cardioversion of spontaneous atrial fibrillation. Immediate and long-term results. Circulation 96:253-259. Notes: Title/abstract: Excluded. Wrong study type.

Li X, Luo R, Hua W, Li L, Kwong-Joey SW, Chan CP, and Yu CM. (2013) Cardiac resynchronization therapy for dilated cardiomyopathy. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong study type.

Linde C, Abraham WT, Gold MR, John Sutton M, Ghio S, and Daubert C. (2008) Randomized Trial of Cardiac Resynchronization in Mildly Symptomatic Heart Failure Patients and in Asymptomatic Patients With Left Ventricular Dysfunction and Previous Heart Failure Symptoms. Journal of the American College of Cardiology 52:1834-1843. Notes: Title/abstract: Included. Full text: Included. REVERSE

Linde C, Abraham WT, Gold MR, John SM, Ghio S, and Daubert C. (2008) Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. Journal of the. American. College. of Cardiology 52:1834-1843. Notes: Duplicate

Linde C, Abraham WT, Gold MR, and Daubert C. (2010) Cardiac resynchronization therapy in asymptomatic or mildly symptomatic heart failure patients in relation to etiology: Results from the reverse (REsynchronization reVErses Remodeling in Systolic Left vEntricular Dysfunction) study. Journal of the American College of Cardiology 56:1826-1831. Notes: Title/abstract: Included. Full text: Included. REVERSE

Linde C, Abraham WT, Gold MR, and Daubert C. (2010) Cardiac resynchronization therapy in asymptomatic or mildly symptomatic heart failure patients in relation to etiology: results from the REVERSE (REsynchronization reVErses Remodeling in Systolic Left vEntricular Dysfunction) study. Journal of the. American. College. of Cardiology 56:1826-1831. Notes: Duplicate

Linde C, Mealing S, Hawkins N, Eaton J, Brown B, and Daubert JC. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure: insights from the European cohort of the REVERSE (Resynchronization Reverses remodeling in Systolic Left Ventricular Dysfunction). European. Heart Journal 32:1631-1639. Notes: Title/abstract: Excluded. Wrong study type

Linde C, Ellenbogen K, and McAlister FA. (2012) Cardiac resynchronization therapy (CRT): Clinical trials, guidelines, and target populations. Heart Rhythm 9:S3-S13. Notes: Title/abstract: Excluded. Wrong study type

Lindenfeld J, Feldman AM, Saxon L, Boehmer J, Carson P, Ghali JK, Anand I, Singh S, Steinberg JS, Jaski B, DeMarco T, Mann D, Yong P, Galle E, Ecklund F, and Bristow M. (2007) Effects of cardiac resynchronization therapy with or without a defibrillator on survival and hospitalizations in patients with New York Heart Association class IV heart failure. Circulation 115:204-212. Notes: Title/abstract: Excluded. Wrong indication.

Lindenfeld J, Feldman AM, Saxon L, Boehmer J, Carson P, Ghali JK, Anand I, Singh S, Steinberg JS, Jaski B, DeMarco T, Mann D, Yong P, Galle E, Ecklund F, and Bristow M. (2007) Effects of cardiac resynchronization therapy with or without a defibrillator on survival and hospitalizations in patients with New York Heart Association class IV heart failure. Circulation 115:204-212. Notes: Duplicate

Link MS, Moss AJ, Goldenburg I, Viskin S, Delnoy PP, Kutz A, McNitt S, Solomon S, Alsheikh-Ali AA, Steinberg J, Estes NA, and Wang PJ. (2010) Prognostic implications of supraventricular tachycardia in CRT-D treated patients: The MADIT-CRT experience. Europace 12:i136. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Link MS, Moss AJ, Goldenberg I, McNitt S, Solomon S, Alsheikh-Ali AA, Steinberg JS, Al-Ahmad A, Estes M, and Wang PJ. (2010) Prognostic implications of atrial tachyarrhythmias in CRT-D treated patients: The MADIT-CRT experience. Heart Rhythm 7:S27. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Loring Z, Strauss DG, Gerstenblith G, Tomaselli GF, Weiss RG, and Wu KC. (2012) Women have less myocardial scar than men: Implications for implantable defibrillators and cardiac resynchronization therapy. Heart Rhythm 9:S372. Notes: Title/abstract: Excluded. Wrong study type.

Lozano I, Bocchiardo M, Achtelik M, Gaita F, Trappe HJ, Daoud E, Hummel J, Duby C, and Yong P. (2000) Impact of biventricular pacing on mortality in a randomized crossover study of patients with heart failure and ventricular arrhythmias. PACE - Pacing and Clinical Electrophysiology 23:1711-1712. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Lozano I, Bocchiardo M, Achtelik M, Gaita F, Trappe HJ, Daoud E, Hummel J, Duby C, and Yong P. (2000) Impact of biventricular pacing on mortality in a randomized crossover study of patients with heart failure and ventricular arrhythmias. Pacing and clinical. electrophysiology. : PACE 23:1711-1712. Notes: Duplicate

Lozano IF and Llorens JLM. (2006) Arrhythmias and cardiac electrophysiology: Main developments in 2005. Revista Espanola de Cardiologia 59:20-30. Notes: Title/abstract: Excluded. Wrong study type.

Lubitz SA, Leong SP, Fine N, Kramer DB, Singh J, and Ellinor PT. (2010) Effectiveness of cardiac resynchronization therapy in mild congestive heart failure: systematic review and meta-analysis of randomized trials (Structured abstract). European. Journal of Heart Failure. 12:360-366. Notes: Title/abstract: Included. Full text: Included. SR

Lunati M, Gasparini M, Bocchiardo M, Curnis A, Landolina M, Carboni A, Luzzi G, Zanotto G, Ravazzi P, Magenta G, Denaro A, Distefano P, and Grammatico A. (2006) Clustering of ventricular tachyarrhythmias in heart failure patients implanted with a biventricular cardioverter defibrillator. Journal of Cardiovascular Electrophysiology 17:1299-1306. Notes: Title/abstract: Excluded. Wrong study type.

Lunati M, Cattafi G, Oliva F, Magenta G, Paolucci M, Vecchi MR, Valsecchi S, Bancala E, Grandi R, and Frigerio M. (2010) Very long term clinical and echocardiographic outcomes of cardiac resynchronization therapy: A single center 10 year experience. European Heart Journal 31:414. Notes: Title/abstract: Excluded. Wrong study type

Lunati M, Cattafi G, Frigerio M, Magenta G, Paolucci M, Vecchi MR, Valsecchi S, Bancala E, Grandi R, Bisetti S, and Oliva F. (2010) Very long term clinical and echocardiographic outcomes of cardiac resynchronization therapy a single center 10 year experience. Europace 12:i136. Notes: Title/abstract: Excluded. Wrong study type

Lunati M, Cattafi G, Oliva F, Magenta G, Paolucci M, Vecchi MR, Fanelli D, Bisetti S, Vimercati M, and Frigerio M. (2010) Over 10 years of cardiac resynchronization therapy a single center experience: Very long term all cause mortality data. Europace 12:i154. Notes: Title/abstract: Excluded. Wrong study type

Lupo PP, Pelissero G, Ali H, Sanghera R, and Cappato R. (2012) Development of an Entirely Subcutaneous Implantable Cardioverter-Defibrillator. Progress in Cardiovascular Diseases 54:493-497. Notes: Title/abstract: Excluded. Wrong study type.

Luqman N, Wang CL, Sung RJ, and Kuo CT. (2008) Emerging role of cardiac resynchronization therapy in heart failure. Acta Cardiologica Sinica 24:1-14. Notes: Title/abstract: Excluded. Wrong study type.

Machado CE, Sweeney MO, Sakaguchi S, Simons GR, Qiao H, Skorupa S, and Hudnall H. (2009) Time to first appropriately treated VT/VF episode in guideline vs. non-guideline primary prevention ICD patients: Preliminary results from the omni study. Heart Rhythm 6:S250. Notes: Title/abstract: Excluded. Wrong study type.

Machado M, Menezes Falcao L, and Ravara L. (2006) Sudden death prevention in heart failure. Revista Portuguesa de Cardiologia 25:727-762. Notes: Title/abstract: Excluded. Wrong study type.

Maines M, Landolina M, Lunati M, Lonardi G, Pappone A, Proclemer A, Zanotto G, Santini M, Varbaro A, Vimercati M, and Valsecchi S. (2010) Intrathoracic and ventricular impedances are associated with changes in ventricular volume in patients receiving defibrillators for CRT. PACE - Pacing and Clinical Electrophysiology 33:64-73. Notes: Title/abstract: Excluded. Wrong study type.

Makki N, Swaminathan PD, and Olshansky B. (2012) Is there a difference in benefits from cardiac resynchronization therapy in ischemic and non-ischemic cardiomyopathy patients? Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Manegold JC, Israel CW, Ehrlich JR, Duray G, Pajitnev D, Wegener FT, and Hohnloser SH. (2007) External cardioversion of atrial fibrillation in patients with implanted pacemaker or cardioverter-defibrillator systems: A randomized comparison of monophasic and biphasic shock energy application. European Heart Journal 28:1731-1738. Notes: Title/abstract: Excluded. Wrong intervention.

Manegold JC, Israel CW, Ehrlich JR, Duray G, Pajitnev D, Wegener FT, and Hohnloser SH. (2007) External cardioversion of atrial fibrillation in patients with implanted pacemaker or cardioverter-defibrillator systems: a randomized comparison of monophasic and biphasic shock energy application. European. Heart Journal 28:1731-1738. Notes: Duplicate

Manolis AS. (2004) Cardiac resynchronization therapy in congestive heart failure: Ready for prime time? Heart Rhythm 1:355-363. Notes: Title/abstract: Excluded. Wrong indication.

Marco T, Wolfel E, Feldman AM, Lowes B, Higginbotham MB, Ghali JK, Wagoner L, Kirlin PC, Kennett JD, Goel S, Saxon LA, Boehmer JP, Mann D, Galle E, Ecklund F, Yong P, and Bristow MR. (2008) Impact of cardiac resynchronization therapy on exercise performance, functional capacity, and quality of life in systolic heart failure with QRS prolongation: COMPANION trial sub-study. Journal of Cardiac. Failure. 14:9-18. Notes: Title/abstract: Excluded. Wrong indication.

Margossian R. (2008) Contemporary management of pediatric heart failure. Expert Review of Cardiovascular Therapy 6:187-197. Notes: Title/abstract: Excluded. Wrong study type.

Mariani JA, Gould PA, Broughton A, and Kaye DM. (2006) Cardiac resynchronisation therapy for heart failure. Internal Medicine Journal 36:114-123. Notes: Title/abstract: Excluded. Wrong study type.

Marijon E, Jacob S, Mouton E, Defaye P, Piot O, Delarche N, Dennetiere S, Galley D, Le Franc P, Appl U, Guyomar Y, Albenque JP, Chevalier P, and Boveda S. (2010) Frequency of atrial tachyarrhythmias in patients treated by cardiac resynchronization (from the Prospective, Multicenter Mona Lisa Study). American Journal of Cardiology 106:688-693. Notes: Title/abstract: Excluded. Wrong study type.

Marijon E, Trinquart L, Otmani A, Leclercq C, Fauchier L, Chevalier P, Klug D, Defaye P, Lellouche N, Mansourati J, Deharo JC, Sadoul N, Anselme F, Maury P, Davy JM, Extramiana F, Hidden-Lucet F, Probst V, Bordachar P, Mansour H, Chauvin M, Jouven X, Lavergne T, Chatellier G, and Le Heuzey JY. (2010) Predictors for short-term progressive heart failure death in New York Heart Association II patients implanted with a cardioverter defibrillator-the EVADEF study. American heart journal 159:659-664. Notes: Title/abstract: Excluded. Wrong study type.

Marshall A, Cheetham A, George RS, Mason M, and Kelion AD. (2012) Cardiac iodine-123 metaiodobenzylguanidine imaging predicts ventricular arrhythmia in heart failure patients receiving an implantable cardioverter-defibrillator for primary prevention. Heart 98:1359-1365. Notes: Title/abstract: Excluded. Wrong study type.

Martin DO, Stolen KQ, Brown S, Yu Y, Christie C, Doshi SK, Smith JM, Gold MR, and Day JD. (2007) Pacing Evaluation-Atrial SUpport Study in Cardiac Resynchronization Therapy (PEGASUS CRT): Design and rationale. American heart journal 153:7-13. Notes: Title/abstract: Excluded. Wrong intervention.

Martin DO, Day JD, Kraus SM, Stolen KQ, and Christman S. (2009) Cardiac resynchronization, not atrial support pacing, improves quality of life in heart failure patients. Journal of Cardiac Failure 15:S70. Notes: Title/abstract: Excluded. Wrong intervention.

Martin DO, Lemke B, Birnie D, Krum H, Lee KLF, Aonuma K, Gasparini M, Starling RC, Milasinovic G, Rogers T, Sambelashvili A, Gorcsan III J, and Houmsse M. (2012) Investigation of a novel algorithm for synchronized left-ventricular pacing and ambulatory optimization of cardiac resynchronization therapy: Results of the adaptive CRT trial. Heart Rhythm 9:1807-1814. Notes: Title/abstract: Excluded. Wrong intervention.

Martin DO, Day JD, Lai PY, Murphy AL, Nayak HM, Villareal RP, Weiner S, Kraus SM, Stolen KQ, and Gold MR. (2012) Atrial support pacing in heart failure: Results from the multicenter PEGASUS CRT trial. Journal of Cardiovascular Electrophysiology 23:1317-1325. Notes: Title/abstract: Excluded. Wrong intervention.

Martin DT, McNitt S, Nesto RW, Rutter MK, and Moss AJ. (2011) Cardiac resynchronization therapy reduces the risk of cardiac events in patients with diabetes enrolled in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). Circulation: Heart Failure 4:332-338. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Martin DT, McNitt S, Nesto RW, Rutter MK, and Moss AJ. (2011) Cardiac resynchronization therapy reduces the risk of cardiac events in patients with diabetes enrolled in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). Circulation. Heart failure. 4:332-338. Notes: Duplicate

Masella C, Zanaboni P, Di Stasi F, Gilardi S, Ponzi P, and Valsecchi S. (2008) Assessment of a remote monitoring system for implantable cardioverter defibrillators. Journal of telemedicine and telecare 14:290-294. Notes: Title/abstract: Excluded. Wrong study type.

McAlister FA, Ezekowitz J, Dryden DM, Hooton N, Vandermeer B, Friesen C, Spooner C, and Rowe BH. (2007) Cardiac resynchronization therapy and implantable cardiac defibrillators in left ventricular

systolic dysfunction. Evidence report/technology assessment1-199. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail

McAlister FA, Ezekowitz J, Hooton N, Vandermeer B, Spooner C, Dryden DM, Page RL, Hlatky MA, and Rowe BH. (2007) Cardiac resynchronization therapy for patients with left ventricular systolic dysfunction: A systematic review. Journal of the American Medical Association 297:2502-2514. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

McAlister FA, Ezekowitz J, Hooton N, Vandermeer B, Spooner C, Dryden DM, Page RL, Hlatky MA, and Rowe BH. (2007) Cardiac resynchronization therapy for patients with left ventricular systolic dysfunction: a systematic review (Structured abstract). JAMA 297:2502-2514. Notes: Duplicate

McAlister FA, Ezekowitz J, Dryden DM, Hooton N, Vandermeer B, Friesen C, Spooner C, and Rowe BH. (2007) Cardiac resynchronization therapy and implantable cardiac defibrillators in left ventricular systolic dysfunction (Structured abstract). Health Technology Assessment. Database.199. Notes: Duplicate

McAlister FA, Wiebe N, Ezekowitz JA, Leung AA, and Armstrong PW. (2009) Meta-analysis: beta-blocker dose, heart rate reduction, and death in patients with heart failure (Structured abstract). Annals. of Internal. Medicine 150:784-794. Notes: Title/abstract: Excluded. Wrong intervention.

Mccomb J, Fernandez-Lozano I, Kacet S, Jung W, Landolina M, Mortensen P, Raatikainen P, Mullens W, Speca GC, and Gazzola C. (2011) Demographic and clinical characteristics of the population enrolled in nullClinical evaluation of remote monitoring with direct alerts to reduce time from event to clinical decision (react)null study. PACE - Pacing and Clinical Electrophysiology 34:1444. Notes: Title/abstract: Excluded. Wrong intervention.

McGrew FA, Johnson EE, Coppess MA, Hamilton B, Charlton SB, Sims JJ, and Charlton TA. (2009) Significant survival benefit in 286 elderly primary prevention patients with implantable cardioverter defibrillators. Journal of Cardiac Failure 15:S103-S104. Notes: Title/abstract: Excluded. Wrong study type.

McMurray JJV and Pfeffer MA. (2005) Heart failure. The Lancet 365:1877-1889. Notes: Title/abstract: Excluded. Wrong study type.

McSwain RL, Schwartz RA, DeLurgio DB, Mera FV, Langberg JJ, and Leon AR. (2005) The impact of cardiac resynchronization therapy on ventricular tachycardia/fibrillation: An analysis from the combined contak-CD and InSync-ICD studies. Journal of Cardiovascular Electrophysiology 16:1168-1171. Notes: Title/abstract: Excluded. Wrong study type.

Medina A, Goldberger H, McNitt S, Zareba W, and Moss AJ. (2012) Relation between bnp and ventricular tachyarrhythmias in the madit-CRT trial. Heart Rhythm 9:S301-S302. Notes: Duplicate

Medina A, Goldenberg I, McNitt S, and Moss WZ. (2012) Relation between atrial and ventricular tachyarrhythmia in the madit-CRT trial. Heart Rhythm 9:S103. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. MADIT-CRT.

Mehra MR and Greenberg BH. (2004) Cardiac resynchronization therapy: Caveat medicus! Journal of the American College of Cardiology 43:1145-1148. Notes: Title/abstract: Excluded. Wrong study type.

Mehra MR, Yancy CW, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, O'Connor CM, Reynolds D, Walsh MN, and Fonarow GC. (2009) Evidence of clinical practice heterogeneity in the use of implantable cardioverter-defibrillators in heart failure and post-myocardial infarction left ventricular dysfunction: Findings from IMPROVE HF. Heart Rhythm 6:1727-1734. Notes: Title/abstract: Excluded. Wrong study type.

Mehta D, Langan MN, and Banker J. (2001) Pacemakers and defibrillators for congestive heart failure. Current Cardiology Reports 3:119-123. Notes: Title/abstract: Excluded. Wrong study type.

Meisel E, Butter C, Philippon F, Higgins S, Strickberger SA, Smith J, Hahn S, Michel U, Schubert B, and Pfeiffer D. (2000) Transvenous biventricular defibrillation. American Journal of Cardiology 86:76K-85K. Notes: Title/abstract: Excluded. Wrong study type.

Meisel E, Butter C, Philippon F, Higgins S, Strickberger SA, Smith J, Hahn S, Michel U, Schubert B, and Pfeiffer D. (2000) Transvenous biventricular defibrillation. The. American. journal of cardiology 86:76K-85K. Notes: Duplicate

Mele D, Toselli T, Pratola C, Artale P, and Ferrari R. (2007) Cardiac resynchronization therapy and mortality reduction in heart failure: A proven association. Giornale Italiano di Cardiologia 8:760-769. Notes: Title/abstract: Excluded. Wrong study type.

Menzies DJ, Lo R, and Steingart RM. (2002) The effect of present day heart failure therapy on sudden death in the elderly. Cardiovascular Reviews and Reports 23:703-711. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B, Vago H, Bartha E, Zima E, Moravcsik E, and Geller L. (2001) Biventicular pacing in patients with severe heart failure. Orvosi hetilap 142:2835-2840. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B. (2005) Latest results of treatment with pacemaker and implantable cardioverter defibrillators. Orvosi hetilap 146:1088-1098. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B, Stockinger J, Girbau JLMI, Zhang Y, Kayser T, Averina VA, Wold ND, and Thomsen PEB. (2009) Daily maximum and median respiratory rate are elevated during clinical events when compared to a post-implant baseline in CRT-D patients. Journal of Cardiac Failure 15:S53. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B, Stockinged J, Mont IG, Zhang Y, Kayser T, Averina V, Wold N, and Bloch Thomsen P. (2009) Daily maximum and median respiratory rate are elevated during clinical events when compared to a post-implant baseline in CRT-D patients. European Journal of Heart Failure, Supplement 8:ii60. Notes: Title/abstract: Excluded. Wrong study type.

Mezzetti M and Saporito D. (2012) Perioperative management of oral anticoagulant therapy in cardiac arrhythmias device implantation. Heart Rhythm 9:S107. Notes: Title/abstract: Excluded. Wrong study type.

Mezzetti M, Saporito D, Caccamo L, De Medeiros D, Marconi M, and Piovaccari G. (2012) Cardiac arrhythmias device implantation during ongoing anticoagulant therapy. Need to change guidelines? European Heart Journal 33:525. Notes: Title/abstract: Excluded. Wrong study type.

Mihalcz A, Kassai I, Foldesi C, Kardos A, and Szili-Torok T. (2010) Sustained benefit at 1-year follow-up from transapical left ventricular endocardial pacing for end-stage heart failure. Journal of Interventional Cardiac Electrophysiology 27:194. Notes: Title/abstract: Excluded. Wrong study type.

Mihalcz A, Kassai I, Foldesi C, Kardos A, and Szili-Torok T. (2010) Sustained benefit AT one year follow up from transapical left ventricular endocardial pacing for end stage heart failure. Heart Rhythm 7:S77. Notes: Title/abstract: Excluded. Wrong study type.

Mihalcz A, Kassai I, Foldesi CS, Kardos A, Abraham P, and Szili-Torok T. (2010) Sustained benefit at one year follow up from transapical left ventricular endocardial pacing for end stage heart failure. European Heart Journal 31:592. Notes: Title/abstract: Excluded. Wrong study type.

Mihalcz A, Kassai I, Foldesi C, Kardos A, and Szili-Torok T. (2010) Sustained benefit at one year follow-up from transapical left ventricular endocardial pacing for end stage heart failure. Journal of the American College of Cardiology 55:A16. Notes: Title/abstract: Excluded. Wrong study type.

Mihalcz A, Kassai I, Kardos A, Foldesi C, and Szili-Torok T. (2010) Sustained benefit at one year follow up from transapical left ventricular endocardial pacing for end stage heart failure. Europace 12:i161. Notes: Title/abstract: Excluded. Wrong study type.

Miller AB, Teerlink J, Carson P, Levy W, Chung E, Gilbert E, Jeffries B, Yadav J, Neville S, Cowart P, Adamson P, and Abraham W. (2012) Impact of remote, wireless pulmonary artery hemodynamic monitoring in patients with atrial fibrillation and chronic heart failure: Insights from the champion trial. Journal of the American College of Cardiology 59:E868. Notes: Title/abstract: Excluded. Wrong study type.

Min X, Meine M, Baker II JH, Pires LA, Turk KT, Horn EM, Kowal RC, Paris M, Park E, and Fain ES. (2007) Estimation of the optimal VV delay by an IEGM-based method in cardiac resynchronization therapy. PACE - Pacing and Clinical Electrophysiology 30:S19-S22. Notes: Title/abstract: Excluded. Wrong study type.

Minden HH and Butter C. (2008) Upgrading to biventricular pacing: Indications and procedural challenges. Herzschrittmachertherapie und Elektrophysiologie 19:38-43. Notes: Title/abstract: Excluded. Wrong study type.

Miranda R, Nault M, Simpson CS, Michael KA, Baranchuk AM, Abdollah H, and Redfearn DP. (2011) Maximal Electrical Separation (MES)-guided placement of right ventricular (RV) lead improves responders in cardiac resynchronization defibrillator therapy (CRT-D). Heart Rhythm 8:S292-S293. Notes: Title/abstract: Excluded. Wrong intervention.

Miranda RI, Simpson CS, Michael KA, Baranchuk AM, Abdollah H, and Redfearn DP. (2011) Maximal electrical separation (MES)-guided placement of right ventricular (RV) lead improves responders in cardiac resynchronization defibrillator therapy (CRT-D). Canadian Journal of Cardiology 27:S263. Notes: Title/abstract: Excluded. Wrong intervention.

Miranda RI, Nault M, Johri A, Simpson CS, Michael KA, Abdollah H, Baranchuk A, and Redfearn DP. (2012) Maximal electric separation-guided placement of right ventricular lead improves responders in cardiac resynchronization defibrillator therapy. Circulation: Arrhythmia and Electrophysiology 5:927-932. Notes: Title/abstract: Excluded. Wrong intervention.

Miranda RI, Nault M, Johri A, Simpson CS, Michael KA, Abdollah H, Baranchuk A, and Redfearn DP. (2012) Maximal electric separation-guided placement of right ventricular lead improves responders in cardiac resynchronization defibrillator therapy. Circulation. Arrhythmia and electrophysiology 5:927-932. Notes: Duplicate

Miyata M, Yoshihisa A, Suzuki S, Yamada S, Kamioka M, Kamiyama Y, Yamaki T, Sugimoto K, Kunii H, Nakazato K, Suzuki H, Saitoh SI, and Takeishi Y. (2011) Adaptive servo ventilation improves cardiac function and prognosis in chronic heart failure patients with cheyne-stokes respiration after cardiac resynchronization therapy. Circulation 124. Notes: Title/abstract: Excluded. Wrong indication.

Miyata M, Yoshihisa A, Suzuki S, Yamada S, Kamioka M, Kamiyama Y, Yamaki T, Sugimoto K, Kunii H, Nakazato K, Suzuki H, Saitoh SI, and Takeishi Y. (2012) Adaptive servo ventilation improves Cheyne-Stokes respiration, cardiac function, and prognosis in chronic heart failure patients with cardiac resynchronization therapy. Journal of Cardiology 60:222-227. Notes: Title/abstract: Excluded. Wrong indication.

Molon G, Di Candia CD, Bongiorni MG, Verlato R, Villani GQ, Mantica M, Rosa CL, D'Onofrio A, Occhetta E, and Botto G. (2010) All-cause mortality in current practice: CRT patients according to trials from companion MADIT CRT. Circulation 122:e234. Notes: Title/abstract: Excluded. Wrong study type.

Momomura SI, Sugi K, Tsutsui H, and Tejima T. (2010) Comparison of cardiac resynchronization therapy outcome between the miracle-icd and Japanese population: MIRACLE-ICD outcome

measured in Japanese indication (MOMIJI) study. Journal of Cardiac Failure 16:S144. Notes: Title/abstract: Excluded. Wrong indication.

Momomura SI, Tsutsui H, Sugawara Y, Ito M, Mitsuhashi T, Fukamizu S, Noro M, Matsumoto N, Tejim T, and Sugi K. (2012) Clinical efficacy of cardiac resynchronization therapy with an implantable defibrillator in a Japanese population - Results of the MIRACLE-ICD outcome measured in Japanese indication (MOMIJI) study -. Circulation Journal 76:1911-1919. Notes: Title/abstract: Excluded. Wrong indication.

Mont IG, Lemke B, Merkely B, Zhang Y, Kayser T, Averina V, Wold N, and Block Thorn Sen P. (2009) Daily maximum and median respiratory rate becomes elevated several weeks before HF hospitalization in patients with implantable devices. European Journal of Heart Failure, Supplement 8:ii9. Notes: Title/abstract: Excluded. Wrong study type.

Mont IG, Lemke B, Merkely B, Zhang Y, Kayser T, Averina V, Wold N, and Bloch Thomsen P. (2009) Daily maximum and median respiratory rate becomes elevated several weeks before HF hospitalization in patients with implantable devices. European Heart Journal 30:1033. Notes: Title/abstract: Excluded. Wrong study type.

Moretti L, Marconi R, Grossi P, Silenzi S, Corradetti P, Pezzuoli ML, and Paliotti D. (2012) Long-term survival of patients with congestive heart failure receiving icd/crt-d devices in a district general hospital. Giornale Italiano di Cardiologia 13:145S.
Notes: Title/abstract: Excluded. Wrong study type.

Moretti L, Marconi R, Marchese P, Grossi P, Silenzi S, and De Santo T. (2012) Long term survival of patients with congestive heart failure receiving ICD/CRT-D devices in a district general hospital. European Heart Journal 33:482. Notes: Title/abstract: Excluded. Wrong study type.

Morgan JM, Gill J, Ng A, Mccomb J, Roderick P, Seed A, Williams S, Witte K, Wright D, and Cowie M. (2012) Economic analysis of a feasibility study of remote monitoring in heart failure (REM-HF-F). Europace 14:iv16. Notes: Title/abstract: Excluded. Wrong study type.

Moss A. (2009) MADIT-CRT: The multicentre automatic defibrillator implantation trial-cardiac resynchronization therapy. European Journal of Heart Failure 11:1217-1219. Notes: Title/abstract: Excluded. Wrong study type.

Moss AJ, Brown MW, Cannom DS, Daubert JP, Estes M, Foster E, Greenberg HM, Hall WJ, Higgins SL, Klein H, Pfeffer M, Wilber D, and Zareba W. (2005) Multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT): Design and clinical protocol. Annals of Noninvasive Electrocardiology 10:34-43. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Moss AJ, Brown MW, Cannom DS, Daubert JP, Estes M, Foster E, Greenberg HM, Hall WJ, Higgins SL, Klein H, Pfeffer M, Wilber D, and Zareba W. (2005) Multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT): design and clinical protocol. Annals. of noninvasive. electrocardiology. : the. official. journal of the. International. Society. for. Holter. and Noninvasive. Electrocardiology. , Inc. 10:34-43. Notes: Duplicate

Moss AJ, Hall WJ, Cannom DS, Klein H, Brown MW, Daubert JP, Estes III NAM, Foster E, Greenberg H, Higgins SL, Pfeffer MA, Solomon SD, Wilber D, and Zareba W. (2009) Cardiac-resynchronization therapy for the prevention of heart-failure events. New England Journal of Medicine 361:1329-1338. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Moss AJ, Hall WJ, Cannom DS, Klein H, Brown MW, Daubert JP, Estes NA, Foster E, Greenberg H, Higgins SL, Pfeffer MA, Solomon SD, Wilber D, and Zareba W. (2009) Cardiac-resynchronization therapy for the prevention of heart-failure events. The. New England. journal of medicine 361:1329-1338. Notes: Duplicate

Moss AJ. (2010) What we have learned from the family of multicenter automatic defibrillator implantation trials. Circulation Journal 74:1038-1041. Notes: Title/abstract: Excluded. Wrong study type

Muk B, Dekany M, Nyolczas N, Szabo B, Ancsin B, Polgar B, Borsanyi T, and Kiss RG. (2011) Assessment of the use of beta-receptor antagonists among patients followed ata heart failure outpatient clinic. European Journal of Heart Failure, Supplement 10:S173-S174. Notes: Title/abstract: Excluded. Wrong study type.

Murgatroyd F, Helmling E, Lemke B, Eber B, Mewis C, Osswald H, Zabel M, Zenker D, and Khalameizer V. (2009) Does capture management cause inappropriate increase in pacing outputs in defibrillators. Heart Rhythm 6:S194. Notes: Title/abstract: Excluded. Wrong study type.

Murgatroyd FD, Helmling E, Lemke B, Eber B, Mewis C, Meer-Hensgens J, Chang Y, Khalameizer V, and Katz A. (2010) Manual vs. automatic capture management in implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. Europace 12:811-816. Notes: Title/abstract: Excluded. Wrong study type.

Muto C, Speca G, Giannola G, Celentano E, Canciello M, Carreras G, Calvanese R, Guidotto T, and Tuccillo B. (2009) Prevalence of ventricular arrhythmias in ICD implanted ischemic patients: Effect of BIV pacing VS RV pacing. Journal of Cardiovascular Electrophysiology 20:S44-S45. Notes: Title/abstract: Excluded. Wrong study type.

Naccarella F, Naccarelli GV, Sdringola Maranga S, Lepera G, Grippo MC, Melandri F, Gatti M, Pazzaglia S, Spinelli G, Angelini V, Ambrosioni E, Borghi C, Giovagnorio MT, and Nisam S. (2002) Do ACE inhibitors or angiotensin II antagonists reduce total mortality and arrhythmic mortality? A critical review of controlled clinical trials. Current Opinion in Cardiology 17:6-18. Notes: Title/abstract: Excluded. Wrong study type.

Naccarelli GV. (2004) Implantable cardioverter-defibrillators: Expanding indications. Current Opinion in Cardiology 19:317-322. Notes: Title/abstract: Excluded. Wrong study type.

Naccarelli GV. (2005) Post myocardial infarction, left ventricular dysfunction, and the expanding role of cardiac implantable electrical devices. Clinical Cardiology 28:I51-I57. Notes: Title/abstract: Excluded. Wrong study type.

Narayan SM. (2005) Implantable defibrillators with and without resynchronization for patients with left ventricular dysfunction. Texas Heart Institute Journal 32:358-361. Notes: Title/abstract: Excluded. Wrong study type.

Navia JL, Atik FA, Grimm RA, Garcia M, Vega PR, Myhre U, Starling RC, Wilkoff BL, Martin D, Houghtaling PL, Blackstone EH, and Cosgrove DM. (2005) Minimally invasive left ventricular epicardial lead placement: Surgical techniques for heart failure resynchronization therapy. Annals of Thoracic Surgery 79:1536-1544. Notes: Title/abstract: Excluded. Wrong study type.

Nayak HM, Verdino RJ, Russo AM, Gerstenfeld EP, Hsia HH, Lin D, Dixit S, Cooper JM, Callans DJ, and Marchlinski FE. (2008) Ventricular tachycardia storm after initiation of biventricular pacing: Incidence, clinical characteristics, management, and outcome. Journal of Cardiovascular Electrophysiology 19:708-715. Notes: Title/abstract: Excluded. Wrong study type

Niazi I, Hayes C, Djelmami-Hani M, Mortada ME, Nangia V, Dhala A, Cooley R, Choudhuri I, Bhatia A, Blanck Z, Jahangir A, Akhtar M, and Sra J. (2012) Lack of proarrhythmia with anodal left ventricular pacing. Heart Rhythm 9:S379. Notes: Title/abstract: Excluded. Wrong study type.

Niazi I, Tomassoni G, Baker J, Corbisiero R, Love C, Martin D, Sheppard R, Worley S, and Harbert N. (2012) Are unipolar pacing thresholds lower than bipolar pacing thresholds in multipolar left ventricular leads? Journal of Cardiac Failure 18:S55. Notes: Title/abstract: Excluded. Wrong study type.

Nicolson WB, Nicolson AE, Smith M, Sandilands AJ, Chin DT, Stafford PJ, Loke I, Pathmanathan RK, Skehan D, and Ng GA. (2012) An atrial channel does not reduce inappropriate ICD therapy rates. Heart Rhythm 9:S298. Notes: Title/abstract: Excluded. Wrong study type.

Noyes K, Veazie P, Hall WJ, Zhao H, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2013) Cost-effectiveness of cardiac resynchronization therapy in the MADIT-CRT trial. Journal of Cardiovascular Electrophysiology 24:66-74. Notes: Title/abstract: Excluded. Wrong study type.

Nurkhanov BM. (1990) The comparative efficacy of a new hydrogel enterosorbent in the detoxification therapy of combined radiation-thermal lesions. Patologicheskaia fiziologiia i Ã¨ksperimental'naia terapiia16-18. Notes: Title/abstract: Excluded. Wrong study type.

O'Connor CM, Fonarow GC, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, Inge PJ, Mehra MR, Reynolds D, Walsh MN, and Yancy CW. (2010) Relationship between cardiology practice teaching status and improvement in the use of evidence-based therapy for heart failure: Findings from improve HF. Journal of the American College of Cardiology 55:A129. Notes: Title/abstract: Excluded. Wrong study type.

Occhetta E, Diotallevi P, Curnis A, Demarchi PG, Giammaria M, Melissano D, Lettica V, Audoglio R, and Ravazzi AP. (2009) Right ventricular bifocal pacing (RVBP) as an alternative to conventional biventricular CRT. Preliminary outcomes of the REFORM-HF randomized pilot study. Journal of Cardiovascular Electrophysiology 20:S43-S44. Notes: Title/abstract: Excluded. Wrong intervention.

Oliva F, Cipriani M, Lunati M, Cattafi G, Masciocco G, Macera F, Turazza F, Fanelli D, Bisetti S, and Frigerio M. (2010) Over 10 years of cardiac resynchronization therapy: A single center experience very long term all cause mortality data. European Journal of Heart Failure, Supplement 9:S185. Notes: Title/abstract: Excluded. Wrong study type

Oliva F, Mortara A, Cacciatore G, Chinaglia A, Di Lenarda A, Gorini M, Metra M, Senni M, Maggioni AP, and Tavazzi L. (2012) Acute heart failure patient profiles, management and in-hospital outcome: Results of the Italian Registry on Heart Failure Outcome. European Journal of Heart Failure 14:1208-1217. Notes: Title/abstract: Excluded. Wrong study type

Oto A, Aytemir K, Canpolat U, Yorgun H, Sunman H, Ulgen A, Demiri E, Gurses KM, Sahiner L, Kaya EB, Tokgozoglu L, and Kabakcnulli G. (2012) Transvenous extraction of pacemaker and implantable cardioverter defibrillator leads using new technology; Evolution(registered trademark) mechanical dilator sheath. International Journal of Cardiology 155:S17. Notes: Title/abstract: Excluded. Wrong study type.

Paisey JR, Yue AM, Moore R, Betts TR, Roberts PR, and Morgan JM. (2005) Development of indications for cardiac resynchronisation therapy in the implantable cardioverter defibrillator population. International Journal of Cardiology 99:187-190. Notes: Title/abstract: Excluded. Wrong study type.

Pak HN, Liu YB, Hayashi H, Okuyama Y, Chen PS, and Lin SF. (2003) Synchronization of ventricular fibrillation with real-time feedback pacing: Implication to low-energy defibrillation. American Journal of Physiology - Heart and Circulatory Physiology 285:H2704-H2711. Notes: Title/abstract: Excluded. Wrong study type.

Pak HN, Okuyama Y, Oh YS, Hayashi H, Liu YB, Chen PS, and Lin SF. (2004) Improvement of defibrillation efficacy with preshock synchronized pacing. Journal of Cardiovascular Electrophysiology 15:581-587. Notes: Title/abstract: Excluded. Wrong study type.

Palazzolo JA, Ellins M, Valenza M, Nery P, Healey JS, Nair GM, Meyer W, Malcolm V, and Morillo CA. (2012) Role of pre-procedural multidetector cardiac CT scan in left ventricular lead placement in Cardiac Resynchronization Therapy (CRT): A pilot study. Canadian Journal of Cardiology 28:S264. Notes: Title/abstract: Excluded. Wrong intervention

Palazzolo JA, Ellins ML, Valenza MC, Nery P, Healey J, Nair GM, Meyer W, Malcolm V, and Morillo CA. (2012) Role of pre procedural multidetector cardiac CT scan in left ventricular lead placement in cardiac resynchronization therapy (CRT): A pilot study. Heart Rhythm 9:S375-S376. Notes: Title/abstract: Excluded. Wrong intervention

Pandya K, Patel MB, Natla J, Dhoble A, Habetler T, Holliday J, Janes R, Punnam SR, Gardiner JC, and Thakur RK. (2009) Predictors of hemodynamic compromise with propofol during defibrillator implantation: A single center experience. Journal of Interventional Cardiac Electrophysiology 25:145-151. Notes: Title/abstract: Excluded. Wrong study type.

Papavasileiou LP, Forleo GB, Panattoni G, Minni V, Della Rocca D, Vecchio F, Mahfouz K, Di Molfetta A, Cioe R, Magliano G, Santini L, and Romeo F. (2011) Effectiveness of cardiac resynchronization therapy in heart failure patients with moderate to severe mitral regurgitation. Journal of Cardiovascular Electrophysiology 22:S60-S61. Notes: Title/abstract: Excluded. Wrong study type.

Pappone C, Vicedomini G, Augello G, Mazzone P, Nardi S, and Rosanio S. (2003) Combining electrical therapies for advanced heart failure: The Milan experience with biventricular pacing-defibrillation backup combination for primary prevention of sudden cardiac death. American Journal of Cardiology 91:74F-80F. Notes: Title/abstract: Excluded. Wrong study type.

Pappone C, Augello G, Rosanio S, Vicedomini G, Santinelli V, Romano M, Agricola E, Maggi F, Buchmayr G, Moretti G, Mika Y, Ben-Haim SA, Wolzt M, Stix G, and Schmidinger H. (2004) First human chronic experience with cardiac contractility modulation by nonexcitatory electrical currents for treating systolic heart failure: Mid-term safety and efficacy results from a multicenter study. Journal of Cardiovascular Electrophysiology 15:418-427. Notes: Title/abstract: Excluded. Wrong study type.

Park KW. (2012) Nonsurgical therapy for heart failure. International Anesthesiology Clinics 50:1-21. Notes: Title/abstract: Excluded. Wrong study type

Parkash R, Thibault B, Sterns L, Sapp JL, Krahn A, Talajic M, Luce M, Yetisir E, Theorem-Patrick P, Wells GA, and Tang ASL. (2011) The fidelis lead fracture occurs more frequently in patients with cardiac resynchronization therapy. Report from the device committee of the resynchronization/defibrillation for ambulatory heart failure (RAFT) study. Heart Rhythm 8:S121-S122. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Patwala AY and Wright DJ. (2005) Device based treatment of heart failure. Postgraduate Medical Journal 81:286-291. Notes: Title/abstract: Excluded. Wrong study type.

Pedersen SS, Den Broek KCV, Theuns DAMJ, Erdman RAM, Alings M, Meijer A, Jordaens L, and Denollet J. (2011) Risk of chronic anxiety in implantable defibrillator patients: A multi-center study. International Journal of Cardiology 147:420-423. Notes: Title/abstract: Excluded. Wrong study type.

Pedretti RF, Laporta A, Masnaghetti S, Raimondo R, Salerno M, Santoro F, and Vaninetti R. (2010) [Prevention of sudden death in heart failure patients: cardiac resynchronization therapy with or without defibrillation back-up]. Giornale italiano di cardiologia (2006) 11:134S-136S. Notes: Title/abstract: Excluded. Wrong study type.

Peinado Peinado R, Torrecilla EG, Ormaetxe J, and Alvarez M. (2008) Spanish Implantable Cardioverter-Defibrillator Registry. Fourth official report of the Spanish society of cardiology working group on implantable cardioverter-defibrillators (2007). Revista Espanola de Cardiologia 61:1191-1203. Notes: Title/abstract: Excluded. Wrong study type

Peinado R, Arenal A, Arribas F, Torrecilla E, Alvarez M, Ormaetxe JM, and Perez-Castellano N. (2005) Spanish Implantable Cardioverter-Defibrillator registry. First official report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2002-2004). Revista Espanola de Cardiologia 58:1435-1449. Notes: Title/abstract: Excluded. Wrong study type

Peinado R, Torrecilla EG, and Ormaetxe J. (2006) Spanish on registry implantable cardioverter defibrilator second official report of the Spanish society of cardiology working group on implantable cardioverter defibrillators (2005). Revista Espanola de Cardiologia 59:1292-1302. Notes: Title/abstract: Excluded. Wrong study type

Perego GB, Landolina M, Vergara G, Lunati M, Zanotto G, Pappone A, Lonardi G, Speca G, Iacopino S, Varbaro A, Sarkar S, Hettrick DA, and Denaro A. (2008) Implantable CRT device diagnostics identify patients with increased risk for heart failure hospitalization. Journal of Interventional Cardiac Electrophysiology 23:235-242. Notes: Title/abstract: Excluded. Wrong study type.

Peters RW and Gold MR. (2000) Pacing for patients with congestive heart failure and dilated cardiomyopathy. Cardiology Clinics 18:55-66. Notes: Title/abstract: Excluded. Wrong study type.

Pflaumer A, Chard R, and Davis AM. (2012) Perspectives in Interventional Electrophysiology in Children and those with Congenital Heart Disease. Electrophysiology in Children. Heart Lung and Circulation 21:413-420. Notes: Title/abstract: Excluded. Wrong study type

Philippon F. (2004) Cardiac resynchronization therapy: Device-based medicine for heart failure. Journal of Cardiac Surgery 19:270-274. Notes: Title/abstract: Excluded. Wrong study type.

Piccini JP, Hellkamp AS, Whellan DJ, Ellis SJ, Keteyian SJ, Cooper L, Kraus WE, Pina IL, and O'Connor CM. (2010) Exercise training and implantable cardioverter defibrillator shocks in patients with heart failure: Results from HF-action. Journal of the American College of Cardiology 55:A10. Notes: Title/abstract: Excluded. Wrong intervention.

Piccirillo G, Magrì D, Carlo S, Laurentis T, Torrini A, Matera S, Magnanti M, Bernardi L, Barillà F, Quaglione R, Ettorre E, and Marigliano V. (2006) Influence of cardiac-resynchronization therapy on heart rate and blood pressure variability: 1-year follow-up. European. Journal of Heart Failure. 8:716-722. Notes: Title/abstract: Excluded. Wrong study type.

Pierantozzi A, Landolina M, Agricola T, Lunati M, Pisano E, Lonardi G, Bardelli G, Proclemer A, Speca G, Zucchi G, Marseglia A, Valsecchi S, and Bocconcelli P. (2011) Automatic adjustment of stimulation output in resynchronization therapy: Impact and effectiveness in clinical practice. Europace 13:1311-1318. Notes: Title/abstract: Excluded. Wrong study type.

Pierantozzi A, Landolina M, Agricola T, Lunati M, Pisanò E, Lonardi G, Bardelli G, Proclemer A, Speca G, Zucchi G, Marseglia A, Valsecchi S, and Bocconcelli P. (2011) Automatic adjustment of stimulation output in resynchronization therapy: impact and effectiveness in clinical practice. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 13:1311-1318. Notes: Duplicate

Pinter A, Mangat I, Korley V, Connolly S, Connors S, Gardner M, Philippon F, Sterns L, Thibault B, and Dorian P. (2009) Assessment of resynchronization therapy on functional status and quality of life in patients requiring an implantable defibrillator. PACE - Pacing and Clinical Electrophysiology 32:1509-1519. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail. Does not report results for NYHA class II.

Pinter A, Mangat I, Korley V, Connolly S, Connors S, Gardner M, Philippon F, Sterns L, Thibault B, and Dorian P. (2009) Assessment of resynchronization therapy on functional status and quality of life in patients requiring an implantable defibrillator. Pacing and clinical. electrophysiology. : PACE 32:1509-1519. Notes: Duplicate

Pires LA, Abraham WT, Young JB, and Johnson KM. (2006) Clinical predictors and timing of New York Heart Association class improvement with cardiac resynchronization therapy in patients with advanced chronic heart failure: Results from the Multicenter InSync Randomized Clinical Evaluation (MIRACLE) and Multicenter InSync ICD Randomized Clinical Evaluation (MIRACLE-ICD) trials. American heart journal 151:837-843. Notes: Title/abstract: Excluded. Wrong indication.

Pires LA. (2006) Implantable devices for management of chronic heart failure: Defibrillators and biventricular pacing therapy. Current Opinion in Anaesthesiology 19:69-74. Notes: Title/abstract: Excluded. Wrong study type.

Pokushalov E, Romanov A, Corbucci G, Prohorova D, Chernyavsky A, Larionov P, Terekhov I, Artyomenko S, Kliver E, Shirokova N, Karaskov A, and Dib N. (2011) Cardiac resynchronization therapy and bone marrow cell transplantation in patients with ischemic heart failure and electromechanical dyssynchrony: A randomized pilot study. Journal of Cardiovascular Translational Research 4:767-778. Notes: Title/abstract: Excluded. Wrong intervention.

Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, Borge R, Gottipaty V, Shinn T, Dan D, Feldman LA, Seide H, Winston SA, Gallagher JJ, Langberg JJ, Mitchell K, and Holcomb R. (2010) Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: Results from the REPLACE registry. Circulation 122:1553-1561. Notes: Title/abstract: Excluded. Wrong study type.

Popov SV, Antonchenko IV, Savenkova GM, and Karpov RS. (2007) Cardioresynchronizing therapy in treatment of cardiac insufficiency. Vestnik Rossiiskoi Akademii Meditsinskikh Nauk46-50. Notes: Title/abstract: Excluded. Wrong study type.

Porterfield JG, Porterfield L, Beau SL, Corbisiero R, Greer GS, Love C, Garcia F, and Kawasaki R. (2010) Evaluation of a new multi-vector impedance based algorithm for detection of pulmonary edema. Heart Rhythm 7:S369. Notes: Title/abstract: Excluded. Wrong study type.

Pouleur AC, Knappe D, Shah AM, Uno H, Bourgoun M, Foster E, McNitt S, Hall WJ, Zareba W, Goldenberg I, Moss AJ, Pfeffer MA, and Solomon SD. (2011) Relationship between improvement in left ventricular dyssynchrony and contractile function and clinical outcome with cardiac resynchronization therapy: The MADIT-CRT trial. European Heart Journal 32:1720-1729. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Pouleur AC, Knappe D, Shah AM, Uno H, Bourgoun M, Foster E, McNitt S, Hall WJ, Zareba W, Goldenberg I, Moss AJ, Pfeffer MA, and Solomon SD. (2011) Relationship between improvement in left ventricular dyssynchrony and contractile function and clinical outcome with cardiac resynchronization therapy: the MADIT-CRT trial. European. Heart Journal 32:1720-1729. Notes: Duplicate

Powell BD, Asirvatham SJ, Perschbacher DL, Jones PW, Cha YM, Cesario DA, Cao M, Gilliam FR, and Saxon LA. (2012) Noise, artifact, and oversensing related inappropriate ICD shock evaluation: ALTITUDE noise study. PACE - Pacing and Clinical Electrophysiology 35:863-869. Notes: Title/abstract: Excluded. Wrong study type.

Proclemer A, Boveda S, Oswald H, Scipione P, Rousseauplasse A, and Da Costa A. (2011) Appraisal of ICD models prescription beyond current guidelines: Results from the FIRST registry. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Prylutska H, Thibault B, Harel F, White M, Fortier A, Guerra PG, and Ducharme A. (2010) Impact of baseline RV structural and functional abnormalities on the presence of cardiac dyssynchrony: insight from the evaluation of resynchronization therapy for heart failure (EARTH) TRIAL. Journal of Heart and Lung Transplantation 29:S163. Notes: Title/abstract: Excluded. Wrong intervention.

Prystowsky EN. (2003) A guide to device selection: Cardiac resynchronization therapy alone or in combination with an implantable cardioverter defibrillator. Reviews in Cardiovascular Medicine 4:S47-S54. Notes: Title/abstract: Excluded. Wrong study type.

Prystowsky EN. (2005) Prevention of sudden cardiac death. Clinical Cardiology 28:I12-I18. Notes: Title/abstract: Excluded. Wrong study type

Prystowsky EN, Fogel RI, Padanilam BJ, and Rardon D. (2009) Implantable Cardioverter Defibrillator Therapy for Primary Prevention of Sudden Cardiac Death-An Argument for Guideline Adherence. Cardiac Electrophysiology Clinics 1:95-103. Notes: Title/abstract: Excluded. Wrong study type.

Przybylski A, Derejko P, Kwasniewski W, Urbanczyk-Swic D, Zakrzewska J, Orszulak W, Orczykowski M, Filipecki A, Szumowski L, Walczak F, and Trusz-Gluza M. (2010) Bleeding complications after pacemaker or cardioverter-defibrillator implantation in patients receiving dual antiplatelet therapy: Results of a prospective, two-centre registry. Netherlands Heart Journal 18:230-235. Notes: Title/abstract: Excluded. Wrong study type.

Pugliese M, Minardi G, Vitali A, Natale E, de Girolamo P, Zampi G, Leggio M, Chiarelli A, Pappalardo A, Avella A, Laurenzi F, and Fera MS. (2012) Influence of myocardial viability on responsiveness to cardiac resynchronization in ischemic dilated cardiomyopathy: A prospective observational cohort study. Anadolu Kardiyoloji Dergisi 12:132-141. Notes: Title/abstract: Excluded. Wrong study type.

Pugliese M, Minardi G, Vitali A, Natale E, de Girolamo P, Zampi G, Leggio M, Chiarelli A, Pappalardo A, Avella A, Laurenzi F, and Fera MS. (2012) Influence of myocardial viability on responsiveness to cardiac resynchronization in ischemic dilated cardiomyopathy: a prospective observational cohort study. Anadolu kardiyoloji dergisi : AKD = the Anatolian journal of cardiology 12:132-141. Notes: Duplicate

Purerfellner H, Nesser HJ, Winter S, Schwierz T, Hornell H, and Maertens S. (2000) Transvenous left ventricular lead implantation with the EASYTRAK lead system: The European experience. American Journal of Cardiology 86:157K-164K. Notes: Title/abstract: Excluded. Wrong study type.

Quinlivan R, Bourke JP, and Bueser T. (2012) Prevention and treatment for cardiac complications in Duchenne and Becker muscular dystrophy and X-linked dilated cardiomyopathy. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong study type.

Quiros FR, Morillo CA, Casas JP, Cubillos LA, and Silva FA. (2006) Charity: Chagas cardiomyopathy bisoprolol intervention study: A randomized double-blind placebo force-titration controlled study with Bisoprolol in patients with chronic heart failure secondary to Chagas cardiomyopathy [NCT00323973]. Trials 7:21. Notes: Title/abstract: Excluded. Wrong indication.

Rademaker MT, Charles CJ, Melton IC, Richards AM, Frampton CM, Siou J, Qu F, Eigler NL, Gutfinger D, and Troughton RW. (2011) Monitoring of heart failure: Comparison of left atrial pressure with intrathoracic impedance and natriuretic peptide measurements in an experimental model of ovine heart failure. Clinical Science 120:207-217. Notes: Title/abstract: Excluded. Wrong study type.

Raja I and Narasimhan C. (2010) Cardiac resynchronisation therapy for heart failure. Heart Surgery Forum 13:S29. Notes: Title/abstract: Excluded. Wrong study type.

Rami T and Shih HT. (2004) Update of implantable cardioverter/defibrillator and cardiac resynchronization therapy in heart failure. Current Opinion in Cardiology 19:264-269. Notes: Title/abstract: Excluded. Wrong study type.

Rao BH and Saksena S. (2003) Implantable cardioverter-defibrillators in cardiovascular care: Technologic advances and new indications. Current Opinion in Critical Care 9:362-368. Notes: Title/abstract: Excluded. Wrong study type.

Ray IB, Fendelander L, and Singh JP. (2007) Cardiac resynchronization therapy and its potential proarrhythmic effect. Clinical Cardiology 30:498-502. Notes: Title/abstract: Excluded. Wrong study type.

Reddy S, Bahl A, and Talwar KK. (2010) Congestive heart failure in Indians: How do we improve diagnosis & management? Indian Journal of Medical Research, Supplement 132:549-560. Notes: Title/abstract: Excluded. Wrong study type.

Reddy S, Bahl A, and Talwar KK. (2010) Congestive heart failure in Indians: How do we improve diagnosis & management? Indian Journal of Medical Research 132:549-560. Notes: Duplicate

Reddy S, Bahl A, and Talwar KK. (2010) Congestive heart failure in Indians: how do we improve diagnosis & management? The Indian journal of medical research 132:549-560. Notes: Duplicate

Retel LK, Slabaugh J, Rott MA, Trohman RG, McGriff DM, and Hauser RG. (2012) Icd pulse generator longevity: Results from the multicenter registry. Heart Rhythm 9:S102. Notes: Title/abstract: Excluded. Wrong study type.

Retel LK, Slabaugh J, Rott M, Trohman R, McGriff D, and Hauser R. (2012) ICD pulse generator longevity: Results from themulticenter registry. Journal of Interventional Cardiac Electrophysiology 33:319. Notes: Title/abstract: Excluded. Wrong study type.

Rey C. (2007) The best of congenital heart disease in 2006. Archives des Maladies du Coeur et des Vaisseaux 100:103-110. Notes: Title/abstract: Excluded. Wrong study type.

Reynolds D, Albert NM, Curtis AB, Gheorghiade M, Heywood JT, McBride ML, Inge PJ, Mehra MR, O'Connor CM, Walsh MN, Yancy CW, and Fonarow GC. (2012) Race and improvements in the use of guideline-recommended therapies for patients with heart failure: Findings from IMPROVE HF. Journal of the National Medical Association 104:287-298. Notes: Title/abstract: Excluded. Wrong study type.

Reynolds MR, Joventino LP, and Josephson ME. (2004) Relationship of baseline electrocardiographic characteristics with the response to cardiac resynchronization therapy for heart failure. PACE - Pacing and Clinical Electrophysiology 27:1513-1518. Notes: Title/abstract: Excluded. Wrong study type.

Reynolds MR, Joventino LP, and Josephson ME. (2004) Relationship of baseline electrocardiographic characteristics with the response to cardiac resynchronization therapy for heart failure. Pacing and clinical. electrophysiology. : PACE 27:1513-1518. Notes: Duplicate

Ricci RP, Morichelli L, Gargaro A, Laudadio MT, and Santini M. (2009) Home monitoring in patients with implantable cardiac devices: Is there a potential reduction of stroke risk? Results from a computer model tested through monte carlo simulations. Journal of Cardiovascular Electrophysiology 20:1244-1251. Notes: Title/abstract: Excluded. Wrong study type.

Ricci RP, Morichelli L, and Santini M. (2009) Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 11:54-61. Notes: Title/abstract: Excluded. Wrong study type.

Rigau CD, Sola A, I, Alonso CP, and Martinez PF. (2008) Efficacy of biventricular pacemakers for heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong indication.

Rivero-Ayerza M, Theuns DAMJ, Garcia-Garcia HM, Boersma E, Simoons M, and Jordaens LJ. (2006) Effects of cardiac resynchronization therapy on overall mortality and mode of death: A meta-analysis of randomized controlled trials. European Heart Journal 27:2682-2688. Notes: Title/abstract: Excluded. Wrong indication.

Rivero A and Curtis AB. (2010) Sex differences in arrhythmias. Current Opinion in Cardiology 25:8-15. Notes: Title/abstract: Excluded. Wrong study type

Rivero AM, Theuns DA, Garcia-Garcia HM, Boersma E, Simoons M, and Jordaens LJ. (2006) Effects of cardiac resynchronization therapy on overall mortality and mode of death: a meta-analysis of randomized controlled trials (Structured abstract). European. Heart Journal 27:2682-2688. Notes: Duplicate

Rollin A, Mondoly P, Boveda S, Combes N, Hebrard A, Delay M, Maury P, Albenque JP, and Duparc A. (2010) Long term response to cardiac resynchronization therapy in elderly patients. European Heart Journal 31:414. Notes: Title/abstract: Excluded. Wrong study type.

Romanov A, Pokushalov E, Corbucci G, Prokhorova D, Shabanov V, Artemenko S, Stenin I, Elesin D, Losik D, and Yakubov A. (2011) Cardiac resynchronization therapy and bone marrow cell transplantation in patients with ischemic heart failure and electro-mechanical dyssynchrony. A randomized pilot study. PACE - Pacing and Clinical Electrophysiology 34:1321-1322. Notes: Title/abstract: Excluded. Wrong intervention.

Rosanio S, Schwarz ER, Ahmad M, Jammula P, Vitarelli A, Uretsky BF, Birnbaum Y, Ware DL, Atar S, and Saeed M. (2005) Benefits, unresolved questions, and technical issues of cardiac resynchronization therapy for heart failure. American Journal of Cardiology 96:710-717. Notes: Title/abstract: Excluded. Wrong study type.

Ross HM and Kocovic DZ. (2004) Cardiac resynchronization therapy for heart failure. Current Treatment Options in Cardiovascular Medicine 6:365-370. Notes: Title/abstract: Excluded. Wrong study type.

Rossi A, Rossi G, Piacenti M, Startari U, Panchetti L, and Morales MA. (2008) The current role of cardiac resynchronization therapy in reducing mortality and hospitalization in heart failure patients: A meta-analysis from clinical trials. Heart and Vessels 23:217-223. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Rossi A, Rossi G, Piacenti M, Startari U, Panchetti L, and Morales MA. (2008) The current role of cardiac resynchronization therapy in reducing mortality and hospitalization in heart failure patients: a meta-analysis from clinical trials (Structured abstract). Heart and Vessels 23:217-223. Notes: Duplicate

Roukoz H, Moss AJ, Anand I, and Adabag S. (2011) Cardiac resynchronization therapy reduces mortality and hospitalization in patients with minimal heart failure: Specific evidence on asymptomatic (NYHA I) patients. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract.

Rouleau JL. (2005) Treatment of congestive heart failure: Present and future. Canadian Journal of Cardiology 21:1084-1088. Notes: Title/abstract: Excluded. Wrong study type.

Rouleau JL. (2011) New and Emerging drugs and device therapies for chronic heart failure in patients with systolic ventricular dysfunction. Canadian Journal of Cardiology 27:296-301. Notes: Title/abstract: Excluded. Wrong study type.

Rowley CP, Bernard ML, Brabham W, Netzler P, Cuoco F, Sturdivant JL, Leman RB, Wharton JM, and Gold MR. (2012) Bleeding complications following pacemaker or internal cardioverter-defibrillator implantation among patients receiving dabigatran. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Rudzinski T. (2004) Electrotherapy of congestive heart failure. Polski Przeglad Kardiologiczny 6:453-455. Notes: Title/abstract: Excluded. Wrong study type.

Russo AM, Wang Y, Curtis J, Al-Khatib S, and Lampert R. (2012) Contemporary patterns of practice and characteristics of patients undergoing defibrillation testing versus those who do not undergo testing at the time of initial implantable cardioverter implantation: Analysis of the NCDR ICD registry. Journal of the American College of Cardiology 59:E704. Notes: Title/abstract: Excluded. Wrong study type.

Sack S, Wende CM, Nagele H, Katz A, Bauer WR, Barr CS, Malinowski K, Schwacke H, Leyva F, Proff J, Berdyshev S, and Paul V. (2011) Potential value of automated daily screening of cardiac resynchronization therapy defibrillator diagnostics for prediction of major cardiovascular events:

Results from Home-CARE (Home Monitoring in Cardiac Resynchronization Therapy) study. European Journal of Heart Failure 13:1019-1027. Notes: Title/abstract: Excluded. Wrong study type.

Saeed M, Neason CG, Razavi M, Chandiramani S, Alonso J, Natarajan S, Ip JH, Peress DF, Ramadas S, and Massumi A. (2010) Programming antitachycardia pacing for primary prevention in patients with implantable cardioverter defibrillators: Results from the PROVE trial. Journal of Cardiovascular Electrophysiology 21:1349-1354. Notes: Title/abstract: Excluded. Wrong study type.

Saeed M, Razavi M, Neason CG, and Petrutiu S. (2011) Rationale and design for programming implantable cardioverterdefibrillators in patients with primary prevention indication to prolong time to first shock (PROVIDE) study. Europace 13:1648-1652. Notes: Title/abstract: Excluded. Wrong intervention.

Saksena S and Nagarakanti R. (2008) The future of implantable defibrillator and cardiac resynchronization therapy trials. Journal of Interventional Cardiac Electrophysiology 23:29-39. Notes: Title/abstract: Excluded. Wrong study type.

Salukhe TV, Francis DP, and Sutton R. (2003) Comparison of medical therapy, pacing and defibrillation in heart failure (COMPANION) trial terminated early; combined biventricular pacemaker-defibrillators reduce all-cause mortality and hospitalization. International Journal of Cardiology 87:119-120. Notes: Title/abstract: Excluded. Wrong study type.

Salukhe TV, Dimopoulos K, and Francis D. (2004) Cardiac resynchronisation may reduce all-cause mortality: Meta-analysis of preliminary COMPANION data with CONTAK-CD, InSync ICD, MIRACLE and MUSTIC. International Journal of Cardiology 93:101-103. Notes: Title/abstract: Excluded. Wrong indication.

Santangeli P, Biase L, Dello RA, Casella M, Bartoletti S, Santarelli P, Pelargonio G, and Natale A. (2010) Meta-analysis: age and effectiveness of prophylactic implantable cardioverter-defibrillators (Structured abstract). Annals. of Internal. Medicine 153:592-599. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Santangeli P, Di Biase L, Pelargonio G, Dello Russo A, Casella M, Bartoletti S, David Burkhardt J, Mohanty P, Santarelli P, and Natale A. (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis. Journal of Interventional Cardiac Electrophysiology 32:125-135. Notes: Title/abstract: Included. Full text: Included. SR

Santangeli P, Biase L, Pelargonio G, Dello RA, Casella M, Bartoletti S, Burkhardt JD, Mohanty P, Santarelli P, and Natale A. (2011) Cardiac resynchronization therapy in patients with mild heart failure: a systematic review and meta-analysis (Structured abstract). Journal of Interventional. Cardiac. Electrophysiology. 32:125-135. Notes: Duplicate

Santini L, Papavasileiou L, Duro L, Magliano G, Tota C, Topa A, Mahfouz K, Della Rocca D, Cioe R, Forleo GB, and Romeo F. (2011) Ropivacaine-lidocaine combination as a local anesthesia during pacemaker and implantable cardioverter defibrillator implantation. Journal of Cardiovascular Electrophysiology 22:S128. Notes: Title/abstract: Excluded. Wrong intervention.

Santini M, Pandozi C, Toscano S, Castro A, Altamura G, Jesi A, and Villani M. (1997) Changes in intracardiac atrial cardioversion threshold at rest and during exercise. Journal of the American College of Cardiology 29:576-581. Notes: Title/abstract: Excluded. Wrong study type.

Santini M, Pandozi C, Toscano S, Castro A, Altamura G, Jesi A, and Villani M. (1997) Changes in intracardiac atrial cardioversion threshold at rest and during exercise. Journal of the. American. College. of Cardiology 29:576-581. Notes: Duplicate

Santini M, Pandozi C, Altamura G, Gentilucci G, Villani M, Scianaro MC, Castro A, Ammirati F, and Magris B. (1999) Single shock endocavitary low energy intracardiac cardioversion of chronic atrial

fibrillation. Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing 3:45-51. Notes: Title/abstract: Excluded. Wrong intervention.

Santini M, Pandozi C, Altamura G, Gentilucci G, Villani M, Scianaro MC, Castro A, Ammirati F, and Magris B. (1999) Single shock endocavitary low energy intracardiac cardioversion of chronic atrial fibrillation. Journal of interventional. cardiac. electrophysiology. : an. international. journal of arrhythmias. and pacing 3:45-51. Notes: Duplicate

Santini M, Ricci R, Pignalberi C, and Ansalone G. (2001) Electrotherapeutic management of patients with heart failure. American journal of cardiovascular drugs : drugs, devices, and other interventions 1:227-231. Notes: Title/abstract: Excluded. Wrong study type.

Santini M, Ricci RP, Lunati M, Landolina M, Perego GB, Marzegalli M, Schirru M, Belvito C, Brambilla R, Guenzati G, Gilardi S, and Valsecchi S. (2009) Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes. Journal of Interventional Cardiac Electrophysiology 24:53-61. Notes: Title/abstract: Excluded. Wrong study type.

Santini M, Gasparini M, Landolina M, Lunati M, Proclemer A, Padeletti L, Catanzariti D, Molon G, Botto GL, La Rocca L, Grammatico A, and Boriani G. (2011) Device-detected atrial tachyarrhythmias predict adverse outcome in real-world patients with implantable biventricular defibrillators. Journal of the American College of Cardiology 57:167-172. Notes: Title/abstract: Excluded. Wrong study type.

Santini M, Gasparini M, Landolina M, Lunati M, Proclemer A, Padeletti L, Catanzariti D, Molon G, Botto GL, Rocca L, Grammatico A, and Boriani G. (2011) Device-detected atrial tachyarrhythmias predict adverse outcome in real-world patients with implantable biventricular defibrillators. Journal of the. American. College. of Cardiology 57:167-172. Notes: Duplicate

Sapel'nikov OV, Latypov RS, Grishin IR, Mareev IV, Saidova MA, and Akchurin RS. (2011) [Antitachycardia and resynchronization devices in the treatment of heart failure and prevention of sudden death]. Kardiologiia 51:60-67. Notes: Title/abstract: Excluded. Wrong study type.

Sarkar S, Koehler J, Vitense H, and Hettrick D. (2010) Novel dynamic heart failure risk score incorporating implanted device diagnostic parameters. Journal of Cardiac Failure 16:S42. Notes: Title/abstract: Excluded. Wrong study type

Sarkar S, Koehler J, Ziegler P, Herr J, and Warman E. (2012) Dynamic risk score identifies when patients are at risk for heart failure hospitalization. Journal of the American College of Cardiology 59:E632. Notes: Title/abstract: Excluded. Wrong study type.

Sasov M, Liska B, Margitfalvi P, Malacky T, Svetlosak M, Goncalvesova E, and Hatala R. (2011) Progression of heart failure in patients with severe systolic LV dysfunction NYHA I/II and CRT. Europace 13. Notes: Title/abstract: Excluded. Wrong study type

Sauer WH and Bristow MR. (2008) The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial in perspective. Journal of Interventional Cardiac Electrophysiology 21:3-11. Notes: Title/abstract: Excluded. Wrong study type.

Sawhney NS, Waggoner AD, Garhwal S, Chawla MK, Osborn J, and Faddis MN. (2004) Randomized prospective trial of atrioventricular delay programming for cardiac resynchronization therapy. Heart rhythm. : the. official. journal of the. Heart Rhythm. Society. 1:562-567. Notes: Title/abstract: Excluded. Wrong intervention.

Saxon LA, Boehmer JP, Hummel J, Kacet S, De Marco T, Naccarelli G, and Daoud E. (1999) Biventricular pacing in patients with congestive heart failure: Two prospective randomized trials. American Journal of Cardiology 83:120D-123D. Notes: Title/abstract: Excluded. Wrong intervention.

Saxon LA, Boehmer JP, Hummel J, Kacet S, Marco T, Naccarelli G, and Daoud E. (1999) Biventricular pacing in patients with congestive heart failure: two prospective randomized trials. The VIGOR CHF and VENTAK CHF Investigators. The. American. journal of cardiology 83:120D-123D. Notes: Duplicate

Saxon LA, Boehmer JP, Hummel J, Kacet S, Marco T, Naccarelli G, and Daoud E. (1999) Biventricular pacing in patients with congestive heart failure: Two prospective randomized trials. American. Journal of Cardiology 83:120D-123D. Notes: Duplicate

Saxon LA, Kumar UN, and De Marco T. (2000) Heart failure and cardiac resynchronization therapies: U.S. experience in the year 2000. Annals of Noninvasive Electrocardiology 5:188-194. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA. (2005) Sudden cardiac death: Epidemiology and temporal trends. Reviews in Cardiovascular Medicine 6:S12-S20. Notes: Title/abstract: Excluded. Wrong study type

Saxon LA, Greenfield RA, Crandall BG, Nydegger CC, Orlov M, and Van Genderen R. (2006) Results of the multicenter RENEWAL(registered trademark) 3 AVT clinical study of cardiac resynchronization defibrillator therapy in patients with paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 17:520-525. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA, Greenfield RA, Crandall BG, Nydegger CC, Orlov M, and Van Genderen R. (2006) Results of the multicenter RENEWAL 3 AVT clinical study of cardiac resynchronization defibrillator therapy in patients with paroxysmal atrial fibrillation. Journal of Cardiovascular Electrophysiology 17:520-525. Notes: Duplicate

Saxon LA, Bristow MR, Boehmer J, Krueger S, Kass DA, Marco TD, Carson P, DiCarlo L, Feldman AM, Galle E, and Ecklund F. (2006) Predictors of sudden cardiac death and appropriate shock in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. Circulation 114:2766-2772. Notes: Title/abstract: Excluded. Wrong indication.

Saxon LA, Bristow MR, Boehmer J, Krueger S, Kass DA, Marco T, Carson P, DiCarlo L, Feldman AM, Galle E, and Ecklund F. (2006) Predictors of sudden cardiac death and appropriate shock in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. Circulation 114:2766-2772. Notes: Duplicate

Saxon LA, Boehmer JP, Neuman S, and Mullin CM. (2007) Remote Active Monitoring in Patients With Heart Failure (RAPID-RF): Design and Rationale. Journal of Cardiac Failure 13:241-246. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA, Olshansky B, Volosin K, Steinberg JS, Lee BK, Tomassoni G, Guarnieri T, Rao A, Yong P, Galle E, Leigh J, Ecklund F, and Bristow MR. (2009) Influence of left ventricular lead location on outcomes in the COMPANION study. Journal of Cardiovascular Electrophysiology 20:764-768. Notes: Title/abstract: Excluded. Wrong indication.

Saxon LA, Hayes DL, Gilliam FR, Heidenreich PA, Day J, Seth M, Meyer TE, Jones PW, and Boehmer JP. (2010) Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: The ALTITUDE survival study. Circulation 122:2359-2367. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA, Gilliam FR, Powell BD, Seth M, Jones PW, and Hayes DL. (2011) Survival after shock therapy for VF in ICD and CRT-D recipients followed on a remote network. Heart Rhythm 8:S288. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA and Wilkoff BL. (2012) CRT or CRT-D devices? The case for 'high energy' devices. Heart Failure Reviews 17:777-779. Notes: Title/abstract: Excluded. Wrong study type.

Schaer BA, Osswald S, Di Valentino M, Soliman OI, Sticherling C, Ten Cate FJ, Jordaens L, and Theuns DA. (2010) Close connection between improvement in left ventricular function by cardiac resynchronization therapy and the incidence of arrhythmias in cardiac resynchronization therapy-

defibrillator patients. European Journal of Heart Failure 12:1325-1332. Notes: Title/abstract: Excluded. Wrong study type.

Schmitt C. (2000) Heart failure and sudden cardiac death: pharmacological and nonpharmacological treatment possibilities from the viewpoint of the rhythmologist. Zeitschrift fÃ¼r Kardiologie 89 Suppl 7:55-59. Notes: Title/abstract: Excluded. Wrong study type.

Schron EB and Domanski MJ. (2003) Implantable devices benefit patients with cardiovascular diseases. The Journal of cardiovascular nursing 18:337-342. Notes: Title/abstract: Excluded. Wrong study type.

Schuchert A. (2009) Telemedicine in pacemaker therapy and follow-up. Herzschrittmachertherapie und Elektrophysiologie 20:164-172. Notes: Title/abstract: Excluded. Wrong study type.

Schueler M, Voss F, Thomas D, Bauer A, Katus HA, and Becker R. (2011) AV delay programming in patients with CRT devices: Fixed or adaptive? A randomized monocenter study. Heart Rhythm 8:S293. Notes: Title/abstract: Excluded. Wrong intervention.

Schuger C, Ellenbogen KA, Faddis M, Knight BP, Yong P, and Sample R. (2006) Defibrillation energy requirements in an ICD population receiving cardiac resynchronization therapy. Journal of Cardiovascular Electrophysiology 17:247-250. Notes: Title/abstract: Excluded. Wrong study type.

Schuger C, Ellenbogen KA, Faddis M, Knight BP, Yong P, and Sample R. (2006) Defibrillation energy requirements in an ICD population receiving cardiac resynchronization therapy. Journal of cardiovascular. electrophysiology. 17:247-250. Notes: Duplicate

Schuger C, Daubert JP, Brown MW, Cannom D, Estes III NAM, Hall WJ, Kayser T, Klein H, Olshansky B, Power KA, Wilber D, Zareba W, and Moss AJ. (2012) Multicenter automatic defibrillator implantation trial: Reduce inappropriate therapy (MADIT-RIT): Background, rationale, and clinical protocol. Annals of Noninvasive Electrocardiology 17:176-185. Notes: Title/abstract: Excluded. Wrong intervention.

Schwab JO, Gasparini M, Anselme F, Mabo P, Peinado R, Lavergne T, Bocchiardo M, Mascioli G, Passardi M, and Mainardis M. (2006) Right ventricular versus biventricular antitachycardia pacing in the termination of ventricular tachyarrhythmia in patients receiving cardiac resynchronization therapy: The ADVANCE CRT-D trial. Journal of Cardiovascular Electrophysiology 17:504-507. Notes: Title/abstract: Excluded. Wrong intervention.

Schwab JO, Gasparini M, Lunati M, Proclemer A, Kaup B, Santi E, Ligorio G, Klersy C, De Sousa J, Okreglicki A, Arenal A, Wijffels M, and Lemke B. (2009) Avoid delivering therapies for nonsustained fast ventricular tachyarrhythmia in patients with implantable cardioverter-defibrillator: The ADVANCE III trial. Journal of Cardiovascular Electrophysiology 20:663-666. Notes: Title/abstract: Excluded. Wrong intervention.

Schwab JO, Gasparini M, Anselme F, Clementy J, Santini M, Martinez Ferrer J, De Santo T, and Santi E. (2009) Changes in arrhythmia occurrence and antitachycardia pacing efficacy during cardiac resynchronization therapy: Results of the advance crt-d substudy. European Heart Journal 30:1012-1013. Notes: Title/abstract: Excluded. Wrong intervention.

Schwab JO, Gasparini M, Lunati M, Proclemer A, Kaup B, Santi E, Ligorio G, Klersy C, Sousa J, Okreglicki A, Arenal A, Wijffels M, and Lemke B. (2009) Avoid delivering therapies for nonsustained fast ventricular tachyarrhythmia in patients with implantable cardioverter/defibrillator: the ADVANCE III Trial. Journal of cardiovascular. electrophysiology. 20:663-666. Notes: Duplicate

Schwab JO. (2010) Optimizing ICD programming for shock reduction. Fundamental and Clinical Pharmacology 24:653-659. Notes: Title/abstract: Excluded. Wrong study type

Shahrzad S, Soleiman NK, Taban S, Alizadeh A, Aslani A, Tavoosi A, and Emkanjoo Z. (2012) The effect of Left Ventricular (LV) remodeling on ventricular arrhythmia in cardiac resynchronization therapy

(CRT-D) patients (Antiarrhythmic Effect of CRT). PACE - Pacing and Clinical Electrophysiology 35:592-597. Notes: Title/abstract: Excluded. Wrong study type.

Shalaby AA, Gorcsan J, Fonarow G, Singh J, Bersohn M, Halilovic J, Gupta M, Sonel A, Saba S, Abraham W, and Kadish A. (2012) Results of the risk trial: Renal function and female gender are strongly associated with early response to cardiac resynchronization therapy. Journal of Cardiac Failure 18:S58. Notes: Title/abstract: Excluded. Wrong study type.

Shimizu A. (2009) Cardiac resynchronization therapy with and without implantable cardioverter-defibrillator. Circulation Journal 73:A29-A35. Notes: Title/abstract: Excluded. Wrong study type.

Shin JH, Metzl MD, Hansen JC, Lazar S, Tsai K, Rich JD, Lang RM, Beshai JF, Nayak HM, Burke MC, and Moss JD. (2012) Increased tricuspid regurgitation after cardiac resynchronization therapy device implantation is associated with reduced likelihood of left ventricular reverse remodeling. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Silva Melchor L, Garcia-Pavia P, and Aso JO. (2006) Cardiac resynchronization therapy and prevention of sudden cardiac death in heart failure. From clinical trials to clinical practice. Revista Espanola de Cardiologia Suplementos 6:59F-70F. Notes: Title/abstract: Excluded. Wrong study type.

Singh B, Russell SD, and Cheng A. (2012) Update on device technologies for monitoring heart failure. Current Treatment Options in Cardiovascular Medicine 14:536-549. Notes: Title/abstract: Excluded. Wrong study type.

Singh J, Beshai JF, Grimm R, Tchou P, and Tomassoni G. (2010) Left ventricular lead position and response to CRT in narrow QRS patients: A RethinQ substudy. Europace 12:i147. Notes: Title/abstract: Excluded. Wrong indication

Singh JP, Beshai JF, Grimm R, Tchou P, and Tomassoni G. (2010) Left ventricular lead position and response to CRT in narrow QRS patients: A rethinq substudy. Heart Rhythm 7:S124. Notes: Title/abstract: Excluded. Wrong indication

Singh JP, Klein HU, Huang DT, Reek S, Kuniss M, Quesada A, Barsheshet A, Cannom D, Goldenberg I, McNitt S, Daubert JP, Zareba W, and Moss AJ. (2011) Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 123:1159-1166. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Singh JP, Klein HU, Huang DT, Reek S, Kuniss M, Quesada A, Barsheshet A, Cannom D, Goldenberg I, McNitt S, Daubert JP, Zareba W, and Moss AJ. (2011) Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. Circulation 123:1159-1166. Notes: Duplicate

Singh JP, Shen J, Chung ES, Martin DO, Abraham WT, and Coles JA. (2012) Clinical response with adaptive CRT algorithm compared with echo guided AV optimization: A propensity score analysis of multi-center trials. European Heart Journal 33:538. Notes: Title/abstract: Excluded. Wrong intervention.

Sipahi I, Carrigan TP, Rowland DY, Stambler BS, and Fang JC. (2011) Impact of QRS duration on clinical event reduction with cardiac resynchronization therapy: meta-analysis of randomized controlled trials (Structured abstract). Archives. of Internal. Medicinedoi. Notes: Title/abstract: Excluded. Wrong intervention.

Sivakumaran ST, Healey J, Rouleau JL, Talajic M, Kimber S, Wells G, and Tang A. (2012) Cardiac resynchronization therapy (CRT) improves clinical outcomes in patients treated with spironolactone in the raft study. Heart Rhythm 9:S154. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Smala A, Gessler M, and Stoepel C. (2011) Demand for routine in office follow-up visits for cardiac implantable electrical devices (CIED) in Germany and the United Kingdom. Value in Health 14:A256. Notes: Title/abstract: Excluded. Wrong study type.

Smala A and Vogtmann T. (2011) Workload in German hospitals caused by routine follow-up services for cardiac implantable electrical devices (CIED). Value in Health 14:A253. Notes: Title/abstract: Excluded. Wrong study type.

Smith MC and Love CJ. (2008) Extraction of transvenous pacing and ICD leads. PACE - Pacing and Clinical Electrophysiology 31:736-752. Notes: Title/abstract: Excluded. Wrong study type

Smith T, Theuns DAMJ, Caliskan K, and Jordaens L. (2011) Long-term follow-up of prophylactic implantable cardioverter-defibrillator- only therapy: Comparison of ischemic and nonischemic heart disease. Clinical Cardiology 34:761-767. Notes: Title/abstract: Excluded. Wrong study type.

Sohaib SM, Chen Z, Manisty C, Francis DP, and Whinnett ZI. (2012) Unbiased assessment of symptomatic nullresponse ratenull to cardiac resynchronization therapy by systematic review of randomised controlled trials. Heart Rhythm 9:S301. Notes: Title/abstract: Excluded. Wrong study type.

Sohaib SMA, Chen Z, Whinnett Z, Francis DP, and Manisty C. (2012) Unbiased assessment of symptomatic nullresponse ratenull to cardiac resynchronisation therapy by systematic review of randomised controlled trials (REVERSE, MIRACLE, MIRACLE ICD, MIRACLE ICD II, CARE-HF, COMPANION, CONTAK-CD, and MUSTIC). Heart 98:A1. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract.

Sohaib SMA, Chen ZC, Whinnett Z, Francis DP, and Manisty C. (2012) Systematic review of genuine symptomatic response to cardiac resynchronization therapy: Acknowledging the contribution of spontaneous response. European Heart Journal 33:995. Notes: Title/abstract: Excluded. Wrong study type.

Solano A, Oddone D, Croci F, Donateo P, Puggioni E, and Brignole M. (2001) Variables of arrhythmia risk in relation to pacemaker and implantable defibrillator. Italian heart journal. Supplement : official journal of the Italian Federation of Cardiology 2:1303-1307. Notes: Title/abstract: Excluded. Wrong study type.

Solano A, Oddone D, Croci F, Donateo P, Puggioni E, and Brignole M. (2001) Arrhythmic risk in relation to pacemaker and implantable defibrillator. Italian Heart Journal Supplement 2:1303-1307. Notes: Title/abstract: Excluded. Wrong study type.

Solik P, Varga I, Lesny P, Luknar M, Babej S, Liska B, and Goncnullalvesova E. (2011) Characteristics and outcomes of patients hospitalized for acute heart failure in Slovakia. Cardiology Letters 20:51S. Notes: Title/abstract: Excluded. Wrong study type.

Solomon SD, Foster E, Bourgoun M, Shah A, Viloria E, Brown MW, Hall WJ, Pfeffer MA, and Moss AJ. (2010) Effect of cardiac resynchronization therapy on reverse remodeling and relation to outcome: Multicenter automatic defibrillator implantation trial: Cardiac resynchronization therapy. Circulation 122:985-992. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT.

Solomon SD, Foster E, Bourgoun M, Shah A, Viloria E, Brown MW, Hall WJ, Pfeffer MA, and Moss AJ. (2010) Effect of cardiac resynchronization therapy on reverse remodeling and relation to outcome: multicenter automatic defibrillator implantation trial: cardiac resynchronization therapy. Circulation 122:985-992. Notes: Duplicate

Sood MM, Pauly RP, Rigatto C, and Komenda P. (2008) Left ventricular dysfunction in the haemodialysis population. NDT Plus 1:199-205. Notes: Title/abstract: Excluded. Wrong study type.

Spencker S, Coban N, Koch L, Schirdewan A, and Mueller D. (2011) Comparison of skin adhesive and absorbable intracutaneous suture for the implantation of cardiac rhythm devices. Europace 13:416-420. Notes: Title/abstract: Excluded. Wrong intervention

Spencker S, Coban N, Koch L, Schirdewan A, and Mueller D. (2011) Comparison of skin adhesive and absorbable intracutaneous suture for the implantation of cardiac rhythm devices. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 13:416-420. Notes: Duplicate

Sperzel J, Goetze S, Kennergren C, Biffi M, Brooke MJ, Vireca E, Saha S, Schubert B, and Butter C. (2009) Performance evaluation of a right atrial automatic capture verification algorithm using two different sensing configurations. PACE - Pacing and Clinical Electrophysiology 32:579-587. Notes: Title/abstract: Excluded. Wrong study type.

Sperzel J, Danschel W, Gutleben KJ, Kranig W, Mortensen P, Connelly D, Trappe HJ, Seidl K, Duray G, Pieske B, Stockinger J, Boriani G, Jung W, Schilling R, Saberi L, Hallier B, Simon M, and Rinaldi CA. (2012) First prospective, multi-centre clinical experience with a novel left ventricular quadripolar lead. Europace 14:365-372. Notes: Title/abstract: Excluded. Wrong study type.

Srivatsa UN, Hoppe BL, Narayan S, Feld GK, and Birgersdotter-Green U. (2007) Ventricular arrhythmia discriminator programming and the impact on the incidence of inappropriate therapy in patients with implantable cardiac defibrillators. Indian Pacing and Electrophysiology Journal 7:77-84. Notes: Title/abstract: Excluded. Wrong study type.

Stabile G, Iuliano A, Turco P, Ciardiello C, and De Simone A. (2009) Cardiac resynchronization therapy: A review of CRT-D versus CRT-P. Future Cardiology 5:567-572. Notes: Title/abstract: Excluded. Wrong study type.

Stabile G, Solimene F, Bertaglia E, Rocca V, Accogli M, Scaccia A, Marrazzo N, Zoppo F, Turco P, Iuliano A, Shopova G, Ciardiello C, and Simone A. (2009) Long-term outcomes of CRT-PM versus CRT-D recipients. Pacing and clinical. electrophysiology. : PACE 32 Suppl 1:S141-S145. Notes: Title/abstract: Excluded. Wrong study type.

Stavrakis S, Lazzara R, and Thadani U. (2011) The benefit of cardiac resynchronization therapy and QRS duration: A meta-analysis. Heart Rhythm 8:S14-S15. Notes: Title/abstract: Excluded. Wrong study type.

Stavrakis S and Thadani U. (2011) The benefit of cardiac resynchronization therapy and QRS duration: a meta-analysis. European Heart Journal 32:141. Notes: Title/abstract: Excluded. Wrong study type.

Stavrakis S, Lazzara R, and Thadani U. (2012) The benefit of cardiac resynchronization therapy and QRS duration: A meta-analysis. Journal of Cardiovascular Electrophysiology 23:163-168. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Steffel J, Holzmeister J, and Abraham WT. (2011) Recent advances in cardiac resynchronization therapy. Postgraduate Medicine 123:18-26. Notes: Title/abstract: Excluded. Wrong study type.

Stein KM, Ellenbogen KA, Gold MR, Lemke B, Lozano IF, Mittal S, Spinale FG, Van Eyk JE, Waggoner AD, and Meyer TE. (2010) SmartDelay determined AV optimization: A comparison of AV delay methods used in cardiac resynchronization therapy (SMART-AV): Rationale and design. PACE - Pacing and Clinical Electrophysiology 33:54-63. Notes: Title/abstract: Excluded. Wrong intervention

Stein KM, Ellenbogen KA, Gold MR, Lemke B, Lozano IF, Mittal S, Spinale FG, Eyk JE, Waggoner AD, and Meyer TE. (2010) SmartDelay determined AV optimization: a comparison of AV delay methods used in cardiac resynchronization therapy (SMART-AV): rationale and design. Pacing and clinical. electrophysiology. : PACE 33:54-63. Notes: Duplicate

Stellbrink C, Auricchio A, Diem B, Breithardt OA, Kloss M, Schondube FA, Klein H, Messmer BJ, and Hanrath P. (1999) Potential benefit of biventricular pacing in patients with congestive heart failure and ventricular tachyarrhythmia. American Journal of Cardiology 83:143D-150D. Notes: Title/abstract: Excluded. Wrong intervention.

Stellbrink C, Auricchio A, Butter C, Sack S, Vogt J, Bocker D, Block M, Kirkels H, and Ramdat-Misier A. (2000) Pacing therapies in congestive heart failure II study. American Journal of Cardiology 86:138K-143K. Notes: Title/abstract: Excluded. Wrong intervention.

Stellbrink C, Auricchio A, Butter C, Sack S, Vogt J, Böcker D, Block M, Kirkels H, and Ramdat MA. (2000) Pacing Therapies in Congestive Heart Failure II study. The. American. journal of cardiology 86:138K-143K. Notes: Duplicate

Stellbrink C. (2005) Cardiac resynchronization therapy - Always with ICD? Herz 30:596-600. Notes: Title/abstract: Excluded. Wrong study type.

Stellbrink C. (2007) Electrotherapy of cardiac failure. Internist 48:961-970. Notes: Title/abstract: Excluded. Wrong study type.

Stellbrink C. (2002) Biventricular stimulation of heart failure - Is there a change of the electrophysiological substrate of ventricluar arrhythmias? Klinikarzt 31:54-57. Notes: Title/abstract: Excluded. Wrong study type.

Sterlinski M, Maciag A, Kowalski O, Goscinska-Bis K, Pytkowski M, Kowalik I, Lewicka-Nowak E, Mitkowski P, Kazmierczak J, Kalarus Z, Kargul W, Lubinski A, Cieslinski A, Kornacewicz-Jach Z, Szwed H, and Sadowski Z. (2007) Mortality in patients with heart failure treated with cardiac resynchronisation therapy. A long-term multi-centre follow-up study. Kardiologia Polska 65:1287-1293. Notes: Title/abstract: Excluded. Wrong study type.

Stewart GC, Kittleson MM, Cowger J, Patel C, Johnson F, Mountis M, Patel P, Rame E, Testani J, Guglin M, Teuteberg J, and Stevenson LW. (2012) High event rates in medically managed advanced heart failure patients followed at VAD centers. Journal of Heart and Lung Transplantation 31:S11-S12. Notes: Title/abstract: Excluded. Wrong study type.

Sticherling C, Schaer B, Coenen M, Kuhne M, Ammann P, and Osswald S. (2006) Cardiac resynchronisation therapy in chronic heart failure. Swiss Medical Weekly 136:611-617. Notes: Title/abstract: Excluded. Wrong study type.

Stockinger J, Staier K, Schiebeling-ROmer J, and Keyl C. (2011) Acute hemodynamic effects of right and left ventricular lead positions during the implantation of cardiac resynchronization therapy defibrillators. PACE - Pacing and Clinical Electrophysiology 34:1537-1543. Notes: Title/abstract: Excluded. Wrong study type.

Stockman D, Leclercq C, Kranig W, Donal E, Calo L, Casella M, Delarche N, Boulogne E, Bouchez D, and Boriani G. (2009) Left univentricular only pacing can be an alternative to biventricular pacing: Results of the randomized, double-blind B-LEFT HF trial. Acta Cardiologica 64:699. Notes: Title/abstract: Excluded. Wrong intervention.

Storti C, Longobardi M, Buzzi MP, Negro MC, Pilun EB, Baldi A, and Falcone C. (2008) Non-pharmacological therapy of decompensated heart failure: cardiac resynchronization therapy. Giornale italiano di cardiologia (2006) 9:123S-128S. Notes: Title/abstract: Excluded. Wrong study type

Sucu M, Davutoglu V, and Ozer O. (2009) Electrical cardioversion. Annals of Saudi Medicine 29:201-206. Notes: Title/abstract: Excluded. Wrong study type.

Suddath WO, Deychak Y, and Varghese PJ. (2001) Electrophysiologic basis by which epinephrine facilitates defibrillation after prolonged episodes of ventricular fibrillation. Annals of Emergency Medicine 38:201-206. Notes: Title/abstract: Excluded. Wrong study type.

Sullivan RM and Olshansky B. (2011) Is a dual-chamber ICD always better in patients requiring an ICD? Cardiac Electrophysiology Clinics 3:577-592. Notes: Title/abstract: Excluded. Wrong study type.

Sumner AD, Boehmer JP, Saxon LA, Carson P, Feldman AM, Galle E, and Bristow MR. (2009) Statin use is associated with improved survival in patients with advanced heart failure receiving resynchronization therapy. Congestive Heart Failure 15:159-164. Notes: Title/abstract: Excluded. Wrong study type.

Sumner AD, Boehmer JP, Saxon LA, Carson P, Feldman AM, Galle E, and Bristow MR. (2009) Statin use is associated with improved survival in patients with advanced heart failure receiving resynchronization therapy. Congestive. heart failure. 15:159-164. Notes: Duplicate

Sun S and Joglar JA. (2011) Cardiac resynchronization therapy: Prospect for long-lasting heart failure remission. Journal of Investigative Medicine 59:887-892. Notes: Title/abstract: Excluded. Wrong study type.

Suzuki A, Shiga T, Yashiro B, Ejima K, Suzuki T, Manaka T, Shoda M, Nakai K, Kasanuki H, and Hagiwara N. (2012) Tpeak-tend dispersion and the occurrence of ventricular tachyarrhythmia in nonischemic heart failure patients receiving cardiac resynchronization therapy. European Heart Journal 33:531. Notes: Title/abstract: Excluded. Wrong study type.

Sweeney MO, Hellkamp AS, Ellenbogen KA, and Lamas GA. (2008) Reduced ejection fraction, sudden cardiac death, and heart failure death in the Mode Selection Trial (MOST): Implications for device selection in elderly patients with sinus node disease. Journal of Cardiovascular Electrophysiology 19:1160-1166. Notes: Title/abstract: Excluded. Wrong study type.

Sweeney MO, Sakaguchi S, Simons G, MacHado C, Connett JE, and Yang F. (2012) Response to the Center for Medicare & Medicaid Services coverage with evidence development request for primary prevention implantable cardioverter-defibrillators: Data from the OMNI study. Heart Rhythm 9:1058-1066. Notes: Title/abstract: Excluded. Wrong study type.

Szabo B, Vagany D, Dekany M, Muk B, Ancsin B, Kiss RG, and Nyolczas N. (2012) Changes in renal function in real-life chronic heart failure patients on optimized therapy. European Heart Journal 33:178-179. Notes: Title/abstract: Excluded. Wrong study type.

Tagney J. (2010) A literature review comparing the experiences and emergent needs of adult patients with permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs). Journal of Clinical Nursing 19:2081-2089. Notes: Title/abstract: Excluded. Wrong study type.

Takaichi S, Sasikala C, Ramana C, Okamura K, and Hiraishi A. (2012) Carotenoids in Rhodoplanes species: Variation of compositions and substrate specificity of predicted carotenogenesis enzymes. Current Microbiology 65:150-155. Notes: Title/abstract: Excluded. Wrong study type.

Talajic M, Yetisir E, Mitchell LB, Luce M, Theoret-Patrick P, Wells GA, and Tang AS. (2011) Adverse events associated with cardiac resynchronization therapy (CRT): Insights from the resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Canadian Journal of Cardiology 27:S243-S244. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Talajic M, Yetisir E, Mitchell. LB, Luce M, Theoret-Patrick P, Wells GA, and Tang AS. (2011) Long-term device-related adverse events after cardiac resynchronization therapy: Insights from the resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Circulation 124. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Talajic M, Gillis AM, Healey JS, Mitchell LB, Sapp JL, Tung S, Gula L, Mielniczuk L, Wells GA, and Tang AS. (2011) Effect of CRT on mode of death in patients with heart failure receiving an ICD: Results from the resynchronization-defibrillation for ambulatory heart failure trial (RAFT). Heart Rhythm 8:S63. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. RAFT.

Tan TC, Sindone AP, and Denniss AR. (2012) Cardiac Electronic Implantable Devices in the Treatment of Heart Failure. Heart Lung and Circulation 21:338-351. Notes: Title/abstract: Excluded. Wrong study type.

Tang AS, Wells GA, Arnold M, Connolly S, Hohnloser S, Nichol G, Rouleau J, Sheldon R, and Talajic M. (2009) Resynchronization/defibrillation for ambulatory heart failure trial: Rationale and trial design. Current Opinion in Cardiology 24:1-8. Notes: Title/abstract: Included. Full text: Included. RAFT

Tang AS, Wells GA, Talajic M, Arnold MO, Sheldon R, Connolly S, Hohnloser SH, Nichol G, Birnie DH, Sapp JL, Yee R, Healey JS, and Rouleau JL. (2010) Cardiac-resynchronization therapy for mild-to-moderate heart failure. The. New England. journal of medicine 363:2385-2395. Notes: Duplicate

Tang ASL, Wells GA, Talajic M, Arnold MO, Sheldon R, Connolly S, Hohnloser SH, Nichol G, Birnie DH, Sapp JL, Yee R, Healey JS, and Rouleau JL. (2010) Cardiac-resynchronization therapy for mild-to-moderate heart failure. New England Journal of Medicine 363:2385-2395. Notes: Title/abstract: Included. Full text: Included. RAFT.

Taylor RS, Dalal H, Jolly K, Moxham T, and Zawada A. (2010) Home-based versus centre-based cardiac rehabilitation. Cochrane. Database. of Systematic. Reviews. Notes: Title/abstract: Excluded. Wrong intervention.

Theodorakis G, Katsikis A, Livanis E, Kostopoulou A, Adamopoulos S, Tsiapras D, and Voudris V. (2011) Long term effects of cardiac resynchronization therapy in non-ambulatory NYHA IV heart failure patients. PACE - Pacing and Clinical Electrophysiology 34:1553-1560. Notes: Title/abstract: Excluded. Wrong study type.

Theuns DA, Smith T, Hunink MG, Bardy GH, and Jordaens L. (2010) Effectiveness of prophylactic implantation of cardioverter-defibrillators without cardiac resynchronization therapy in patients with ischaemic or non-ischaemic heart disease: a systematic review and meta-analysis (Structured abstract). Europace. 12:1564-1570. Notes: Duplicate

Theuns DAMJ, Thornton AS, Klootwijk APJ, Scholten MF, Vantrimpont PJMJ, Balk AHMM, and Jordaens LJ. (2005) Outcome in patients with an ICD incorporating cardiac resynchronisation therapy: Differences between primary and secondary prophylaxis. European Journal of Heart Failure 7:1027-1032. Notes: Title/abstract: Excluded. Wrong study type

Theuns DAMJ, Smith T, Hunink MGM, Bardy GH, and Jordaens L. (2010) Effectiveness of prophylactic implantation of cardioverter-defibrillators without cardiac resynchronization therapy in patients with ischaemic or non-ischaemic heart disease: A systematic review and meta-analysis. Europace 12:1564-1570. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Thibault B, Ducharme A, Harel F, White M, O'Meara E, Roy D, Talajic M, and Khairy P. (2011) Resynchronization therapy does not help heart failure patients with a QRS duration <120 ms. European Heart Journal 32:148. Notes: Title/abstract: Excluded. Wrong indication.

Thijssen J, Borleffs CJW, Delgado V, Van Rees JB, Mooyaart EAQ, Van Bommel RJ, Van Erven L, Boersma E, Bax JJ, and Schalij MJ. (2011) Implantable cardioverter-defibrillator patients who are upgraded and respond to cardiac resynchronization therapy have less ventricular arrhythmias compared with nonresponders. Journal of the American College of Cardiology 58:2282-2289. Notes: Title/abstract: Excluded. Wrong study type.

Thijssen J, Van Den Akker ME, Borleffs CJW, Van Rees JB, De Bie MK, Van Der Velde ET, Van Erven L, and Schalij MJ. (2011) Cost-effectiveness of prophylactic cardioverter defibrillator implantation in a large single center cohort. European Heart Journal 32:312. Notes: Title/abstract: Excluded. Wrong study type

Thijssen J, Van Rees JB, Venlet J, Borleffs CJW, Hoke U, Putter H, Van Der Velde ET, Van Erven L, and Schalij MJ. (2012) The mode of death in implantable cardioverter-defibrillator and cardiac

resynchronization therapy with defibrillator patients: Results from routine clinical practice. Heart Rhythm 9:1605-1612. Notes: Title/abstract: Excluded. Wrong study type.

Timmermans C, Rodriguez LM, Ayers GM, Siu A, Smeets J, Barenbrug P, and Wellens HJ. (2000) Design and preliminary data of the Metrix(TM) atrioverter expanded indication trial. Journal of Interventional Cardiac Electrophysiology 4:197-199. Notes: Title/abstract: Excluded. Wrong indication.

Timoteo AT, Oliveira MM, Silva MN, Cunha PS, Feliciano J, Silva S, and Ferreira RC. (2010) Survival in patients with an implanted cardioverter-defibrillator. Does age matters? European Heart Journal, Supplement 12:F6-F7. Notes: Title/abstract: Excluded. Wrong study type.

Tomaske M, Gerritse B, Kretzers L, Pretre R, Dodge-Khatami A, Rahn M, and Bauersfeld U. (2008) A 12-Year Experience of Bipolar Steroid-Eluting Epicardial Pacing Leads in Children. Annals of Thoracic Surgery 85:1704-1711. Notes: Title/abstract: Excluded. Wrong study type.

Tomassoni G, Baker J, Corbisiero R, Love C, Martin D, Niazi I, Sheppard R, and Worley S. (2011) Post operative performance of a novel left ventricular quadripolar electrode lead. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Tomassoni GF, Baker J, Corbisiero R, Love C, Martin D, Niazi I, Sheppard R, Worley S, Beau S, Greer GS, and Harbert N. (2011) Post operative performance of a novel left ventricular quadripolar electrode lead. Heart Rhythm 8:S119-S120. Notes: Title/abstract: Excluded. Wrong study type.

Tomassoni GF, Baker J, Corbisiero R, Love C, Martin D, Niazi I, Sheppard R, Worley S, Beau S, Greer S, and Harbert N. (2012) Chronic performance of the quartettm left ventricular lead. Heart Rhythm 9:S235. Notes: Title/abstract: Excluded. Wrong study type.

Torre-Amione G, Estep JD, Bhimaraj A, Khalil N, Alo K, Rosenberg SP, Ness LL, and Farazi TG. (2012) A pilot study to evaluate the safety and feasibility of spinal cord stimulation in patients with advanced heart failure. Journal of Cardiac Failure 18:S59.
Notes: Title/abstract: Excluded. Wrong intervention.

Toste A, Soares R, Feliciano J, Andreozzi V, Silva S, Abreu A, Ramos R, Santos N, Ferreira L, and Ferreira RC. (2011) Prognostic value of a new cardiopulmonary exercise testing parameter in chronic heart failure: Oxygen uptake efficiency at peak exercise - Comparison with oxygen uptake efficiency slope. Revista Portuguesa de Cardiologia 30:781-787. Notes: Title/abstract: Excluded. Wrong study type.

Trappe HJ and Gummert J. (2011) Current pacemaker and defibrillator therapy. Deutsches Arzteblatt 108:372-380. Notes: Title/abstract: Excluded. Wrong study type.

Trohman PRG, Kim MH, and Pinski SL. (2004) Cardiac pacing: The state of the art. The Lancet 364:1701-1719. Notes: Title/abstract: Excluded. Wrong study type

Tse HF, Lau CP, Sra JS, Crijns HJGM, Edvardsson N, Kacet S, and Wyse DG. (1999) Atrial fibrillation detection and R-wave synchronization by metrix implantable atrial defibrillator: Implications for long-term efficacy and safety. Circulation 99:1446-1451. Notes: Title/abstract: Excluded. Wrong study type.

Tu R, Zhong G, Zeng Z, Wu W, Wu H, Cao X, and Aung LHH. (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis of randomized controlled trials. Cardiovascular Drugs and Therapy 25:331-340. Notes: Title/abstract: Included. Full text: Included. SR

Tu R, Zhong G, Zeng Z, Wu W, Wu H, Cao X, and Aung LH. (2011) Cardiac resynchronization therapy in patients with mild heart failure: a systematic review and meta-analysis of randomized controlled trials (Structured abstract). Cardiovascular. Drugs and Therapy. 25:331-340. Notes: Duplicate

Tung P and Albert CM. (2013) Causes and prevention of sudden cardiac death in the elderly. Nature Reviews Cardiology. Notes: Title/abstract: Excluded. Wrong study type.

Turcott RG, Das AK, and Ashley EA. (2009) Re: A prospective randomized evaluation of VV delay optimization in CRT-D recipients: echocardiographic observations from the RHYTHM II ICD study. Pacing and clinical electrophysiology : PACE 32:1360-1361. Notes: Title/abstract: Excluded. Wrong study type.

Turcott RG, Witteles RM, Wang PJ, Vagelos RH, Fowler MB, and Ashley EA. (2010) Measurement precision in the optimization of cardiac resynchronization therapy. Circulation. Heart failure. 3:395-404. Notes: Title/abstract: Excluded. Wrong study type.

Turer AT and Rao SV. (2005) Device therapy in the management of congestive heart failure. Cardiology in Review 13:130-138. Notes: Title/abstract: Excluded. Wrong study type.

Upadhyay GA, Choudhry NK, Auricchio A, Ruskin J, and Singh JP. (2008) Cardiac resynchronization in patients with atrial fibrillation: a meta-analysis of prospective cohort studies (Structured abstract). Journal of the. American. College. of Cardiology 52:1239-1246. Notes: Title/abstract: Excluded. Wrong indication.

Val-Mejias JE, Doshi SK, Kroll M, Oza AL, and Shah S. (2009) Is the time constant of the cardiac cell membrane affected by progression of heart disease? Heart Rhythm 6:S442. Notes: Title/abstract: Excluded. Wrong study type.

Val-Mejias JE and Oza A. (2010) Does defibrillation threshold increase as left ventricular ejection fraction decreases? Europace 12:385-388. Notes: Title/abstract: Excluded. Wrong study type.

Val-Mejias JE and Lee K. (2010) What determines the cycle length of the induced ventricular fibrillation during DFT testing? Europace 12:i90. Notes: Title/abstract: Excluded. Wrong study type

Valadri R, Veledar E, Blanco R, Vest R, Gutmann R, Dudley SC, Zafari MA, London B, and Bloom HL. (2012) Evidence for the disparity in implantable cardioverter defibrillator efficacy in patients above 60 years and below 60 years. Journal of Cardiac Failure 18:S51-S52. Notes: Title/abstract: Excluded. Wrong study type.

Valzania C, Eriksson MJ, Boriani G, and Gadler F. (2008) Cardiac resynchronization therapy during rest and exercise: Comparison of two optimization methods. Europace 10:1161-1169. Notes: Title/abstract: Excluded. Wrong intervention.

Valzania C, Eriksson MJ, Boriani G, and Gadler F. (2008) Cardiac resynchronization therapy during rest and exercise: comparison of two optimization methods. Europace. : European. pacing, arrhythmias. , and cardiac. electrophysiology. : journal of the. working. groups. on cardiac. pacing, arrhythmias. , and cardiac. cellular. electrophysiology. of the. European. Society. of Cardiology 10:1161-1169. Notes: Duplicate

Van Gelder IC, Smit MD, Nieuwland W, and Van Veldhuisen DJ. (2006) Non-pharmacological treatment of heart failure: Implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy. Nederlands Tijdschrift voor Geneeskunde 150:2238-2244. Notes: Title/abstract: Excluded. Wrong study type

Van Rees JB, De Bie MK, Thijssen J, Borleffs CJW, Schalij MJ, and Van Erven L. (2011) Implantation-related complications of implantable cardioverter- defibrillators and cardiac resynchronization therapy devices: A systematic review of randomized clinical trials. Journal of the American College of Cardiology 58:995-1000. Notes: Title/abstract: Excluded. Wrong study type.

Van Veldhuisen DJ. (2003) Unanswered questions in the treatment of heart failure. European Heart Journal, Supplement 5:I39-I43. Notes: Title/abstract: Excluded. Wrong study type.

Van Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, Kautzner J, Munoz Aguilera R, Lunati M, Yu CM, Gerritse B, and Borggrefe M. (2011) Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. Circulation 124:1719-1726. Notes: Title/abstract: Excluded. Wrong intervention.

Van Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, Kautzner J, Aguilera RM, Lunati M, Yu CM, Gerritse B, and Borggrefe M. (2011) Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. Journal of Cardiac Failure 17:972. Notes: Title/abstract: Excluded. Wrong intervention.

Vanderheyden M, Blommaert D, Gras D, Calo L, Islam N, Pfeiffer D, Goodman J, Bouchez D, Guzzo L, and Abraham W. (2009) Baseline characteristics of patients randomized in the FREEDOM study. Acta Cardiologica 64:701. Notes: Title/abstract: Excluded. Wrong intervention.

Vanderheyden M, Houben R, Verstreken S, Stahlberg M, Reiters P, Kessels R, and Braunschweig F. (2010) Continuous monitoring of intrathoracic impedance and right ventricular pressures in patients with heart failure. Circulation: Heart Failure 3:370-377. Notes: Title/abstract: Excluded. Wrong study type.

Vanderheyden M, Houben R, Verstreken S, Ståhlberg M, Reiters P, Kessels R, and Braunschweig F. (2010) Continuous monitoring of intrathoracic impedance and right ventricular pressures in patients with heart failure. Circulation. Heart failure. 3:370-377. Notes: Duplicate

Vanderheyden M, Blommaert D, Gras D, Abraha WT, Boulogne E, and Bouchez D. (2011) Left ventricular lead adverse events observed at 1-year FU in the multicenter randomized FREEDOM trial. Acta Cardiologica 66:679. Notes: Title/abstract: Excluded. Wrong intervention.

Vandervoort P, Vercammen J, Jacobs L, Rondelez K, Rivero-Ayerzo M, De Vusser PH, and Mullens W. (2011) Integrating telemonitoring in heart failure disease management: The Genk experience. Acta Cardiologica 66:680-681. Notes: Title/abstract: Excluded. Wrong study type.

Varma N. (2009) Therapeutic implications of automatic home monitoring of implantable cardiac devices. Current Treatment Options in Cardiovascular Medicine 11:366-372. Notes: Title/abstract: Excluded. Wrong study type

Varosy PD, Pellegrini CN, Yang Y, Heidenreich PA, Singh R, Rumsfeld J, and Massie BM. (2010) Real-world incidence of long-term surgical and mechanical complications among veterans WITH implantable cardioverter-defibrillators. Heart Rhythm 7:S377. Notes: Title/abstract: Excluded. Wrong study type.

Veazie PJ, Noyes K, Li Q, Hall WJ, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2012) Cardiac resynchronization and quality of life in patients with minimally symptomatic heart failure. Journal of the American College of Cardiology 60:1940-1944. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Veldhuisen DJ, Braunschweig F, Conraads V, Ford I, Cowie MR, Jondeau G, Kautzner J, Aguilera RM, Lunati M, Yu CM, Gerritse B, and Borggrefe M. (2011) Intrathoracic impedance monitoring, audible patient alerts, and outcome in patients with heart failure. Circulation 124:1719-1726. Notes: Duplicate

Velez M, Hetzel S, Linde C, and Sweitzer N. (2012) Effect of diabetes mellitus on the reverse remodeling response and clinical outcomes with cardiac resynchronization therapy in mildly symptomatic and asymptomatic heart failure patients: A sub-study of the reverse trial. Journal of the American College of Cardiology 59:E1047. Notes: Title/abstract: Excluded. Wrong study type. Conference abstract. REVERSE

Verma A, Wulffhart Z, Lakkireddy D, Khaykin Y, Kaplan A, Sarak B, Biria M, Pillarisetti J, Bhat P, Di Biase L, Constantini O, Quan K, and Natale A. (2010) Incidence of left ventricular function

improvement after primary prevention ICD implantation for non-ischaemic dilated cardiomyopathy: A multicentre experience. Heart 96:510-515. Notes: Title/abstract: Excluded. Wrong study type.

Versteeg H, Van Den Broek K, Theuns D, Mommersteeg P, Alings M, Van Der Voort P, Jordaens L, and Pedersen S. (2011) No health status benefits of crt-d compared to icd-only in the first year following implantation: A multi-center prospective study. Heart Rhythm 8:S158. Notes: Title/abstract: Excluded. Wrong study type.

Versteeg H, Van Den Broek KC, Theuns DAMJ, Mommersteeg PMC, Alings M, Van Der Voort PH, Jordaens L, and Pedersen SS. (2011) Effect of cardiac resynchronization therapy-defibrillator implantation on health status in patients with mild versus moderate symptoms of heart failure. American Journal of Cardiology 108:1155-1159. Notes: Title/abstract: Excluded. Wrong study type.

Vesty J, Rasmusson KD, Hall J, Schmitz S, and Brush S. (2004) Cardiac resynchronization therapy and automatic implantable cardiac defibrillators in the treatment of heart failure: a review article. Journal of the American Academy of Nurse Practitioners 16:441-450. Notes: Title/abstract: Excluded. Wrong study type.

Villani GQ, Nollo G, Ravelli F, Piepoli M, and Capucci A. (2002) Capture of atrial fibrillation reduces the atrial defibrillation threshold. Pacing and clinical. electrophysiology. : PACE 25:1159-1165. Notes: Title/abstract: Excluded. Wrong study type.

Vitovec J and Spinar J. (2008) Management of chronic heart failure. Cor et Vasa 50:259-267. Notes: Title/abstract: Excluded. Wrong study type

Vollmann D, Nagele H, Schauerte P, Wiegand U, Butter C, Zanotto G, Quesada A, Guthmann A, Hill MRS, and Lamp B. (2007) Clinical utility of intrathoracic impedance monitoring to alert patients with an implanted device of deteriorating chronic heart failure. European Heart Journal 28:1835-1840. Notes: Title/abstract: Excluded. Wrong study type

Waintraub X, Chachoua K, Lepillier A, Otmani A, Lavergne T, and Le Heuzey JY. (2008) Cardiac resynchronization therapy: Main trials. Medecine Therapeutique - Cardio 4:6-16. Notes: Title/abstract: Excluded. Wrong study type.

Walsh MN, Yancy CW, Albert NM, Curtis AB, Gheorghiade M, Heywood JT, Inge PJ, McBride ML, Mehra MR, O'Connor CM, Reynolds D, and Fonarow GC. (2010) Equitable improvement for women and men in the use of guideline-recommended therapies for heart failure: Findings from IMPROVE HF. Journal of Cardiac Failure 16:940-949. Notes: Title/abstract: Excluded. Wrong study type.

Walsh MN, Yancy CW, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, Mehra MR, O'Connor CM, Reynolds D, and Fonarow GC. (2010) Electronic health records and quality of care for heart failure. American heart journal 159:635-642. Notes: Title/abstract: Excluded. Wrong study type.

Walsh MN, Fonarow GC, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, O'Connor CM, Inge PJ, Mehra MR, Reynolds D, and Yancy CW. (2010) Equitable improvement for women and men in the use of guideline-recommended therapies for heart failure: Findings from improve HF. Journal of the American College of Cardiology 55:A142. Notes: Title/abstract: Excluded. Wrong study type.

Wase A. (2007) Elevated Defibrillation Thresholds With Biventricular Pacing. Heart Rhythm 4:253. Notes: Title/abstract: Excluded. Wrong study type.

Webster TA, Brooke KL, Hodge DO, Hayes DL, and Cha YM. (2010) Cardiac sympathetic reserve and response to cardiac resynchronization therapy. Journal of Cardiac Failure 16:S47. Notes: Title/abstract: Excluded. Wrong study type.

Weeke P, Johansen JB, Jorgensen OD, Nielsen JC, Moller M, Videbaek R, Hojgaard MV, Riahi S, and Jacobsen PK. (2012) Mortality, appropriate and inappropriate shock in patients with ischemic heart

disease and implantable cardioverter-defibrillators for primary prevention: A nationwide cohort study. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Wellens HJ, Lau CP, Lüderitz B, Akhtar M, Waldo AL, Camm AJ, Timmermans C, Tse HF, Jung W, Jordaens L, and Ayers G. (1998) Atrioverter: an implantable device for the treatment of atrial fibrillation. Circulation 98:1651-1656. Notes: Duplicate

Wellens HJJ, Lau CP, Luderitz B, Akhtar M, Waldo AL, Camm AJ, Timmermans C, Tse HF, Jung W, Jordaens L, and Ayers G. (1998) Atrioverter: An implantable device for the treatment of atrial fibrillation. Circulation 98:1651-1656. Notes: Title/abstract: Excluded. Wrong study type.

Wells G and Little WC. (2004) Heart failure: 20 Years of progress. Cardiology Review 21:14-17. Notes: Title/abstract: Excluded. Wrong study type.

Wells G, Parkash R, Healey JS, Talajic M, Arnold JM, Sullivan S, Peterson J, Yetisir E, Theoret-Patrick P, Luce M, and Tang ASL. (2011) Cardiac resynchronization therapy: A meta-analysis of randomized controlled trials. CMAJ 183:421-429. Notes: Title/abstract: Included. Full text: Included. SR

Wells G, Parkash R, Healey JS, Talajic M, Arnold JM, Sullivan S, Peterson J, Yetisir E, Theoret PP, Luce M, and Tang AS. (2011) Cardiac resynchronization therapy: a meta-analysis of randomized controlled trials (Structured abstract). CMAJ. : Canadian. Medical. Association. Journal 183:421-429. Notes: Duplicate

Wells GA, Coyle D, Nichol G, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Heart Rhythm 9:S71. Notes: Title/abstract: Excluded. Wrong study type.

Wells GA, Coyle D, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Canadian Journal of Cardiology 28:S419. Notes: Title/abstract: Excluded. Wrong study type.

Wexler R, Elton T, Pleister A, and Feldman D. (2009) Cardiomyopathy: An overview. American Family Physician 79:778-784. Notes: Title/abstract: Excluded. Wrong study type.

Whellan DJ, O'Connor CM, Ousdigian KT, and Lung TH. (2008) Rationale, design, and baseline characteristics of a Program to Assess and Review Trending INformation and Evaluate CorRelation to Symptoms in Patients with Heart Failure (PARTNERS HF). American heart journal 156:833-839. Notes: Title/abstract: Excluded. Wrong study type.

Whellan DJ, Ousdigian KT, Al-Khatib SM, Pu W, Sarkar S, Porter CB, Pavri BB, and O'Connor CM. (2010) Combined Heart Failure Device Diagnostics Identify Patients at Higher Risk of Subsequent Heart Failure Hospitalizations. Results From PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) Study. Journal of the American College of Cardiology 55:1803-1810. Notes: Title/abstract: Excluded. Wrong study type.

Wiegand U, Lamp B, Nagele H, Schauerte P, Al Kandari F, Zanotto G, Haass M, Fritsch S, Butter C, Quesada A, Landolina M, Nadurata V, Schwab JO, Muntean B, and Vollmann D. (2010) Device-based monitoring of thoracic impedance for heart failure management: Results of the insync sentry registry. Europace 12:i51. Notes: Title/abstract: Excluded. Wrong study type.

Wikstrom G, Blomström LC, Andren B, Lönnerholm S, Blomström P, Freemantle N, Remp T, and Cleland JG. (2009) The effects of aetiology on outcome in patients treated with cardiac resynchronization therapy in the CARE-HF trial. European. Heart Journal 30:782-788. Notes: Title/abstract: Excluded. Wrong intervention.

Wilkoff BL. (2003) The Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial: rationale, design, results, clinical implications and lessons for future trials. Cardiac electrophysiology review 7:468-472. Notes: Title/abstract: Excluded. Wrong study type.

Wilkoff BL. (2003) The Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial: rationale, design, results, clinical implications and lessons for future trials. Cardiac. electrophysiology. review 7:468-472. Notes: Duplicate

Wilkoff BL, Hess M, Young J, and Abraham WT. (2004) Differences in tachyarrhythmia detection and implantable cardioverter defibrillator therapy by primary or secondary prevention indication in cardiac resynchronization therapy patients. Journal of Cardiovascular Electrophysiology 15:1002-1009. Notes: Title/abstract: Excluded. Wrong study type.

Wilkoff BL, Hess M, Young J, and Abraham WT. (2004) Differences in tachyarrhythmia detection and implantable cardioverter defibrillator therapy by primary or secondary prevention indication in cardiac resynchronization therapy patients. Journal of cardiovascular. electrophysiology. 15:1002-1009. Notes: Duplicate

Wilkoff BL, Stern R, Williamson B, Wathen M, Holloman K, Fieberg A, and Brown M. (2006) 1Design of the Primary Prevention Parameters Evaluation (PREPARE) trial of implantanblecardioverter debfibrillators to reduce patient morbidity [NCT00279279]. Trials 7. Notes: Title/abstract: Excluded. Wrong study type.

Wolber T, Fauchere I, Moini A, Haegeli L, and Duru F. (2012) Safety of rfid gates at ski resorts for patients with implanted cardioverter-defibrillators. Journal fur Kardiologie 19:184. Notes: Title/abstract: Excluded. Wrong study type.

Wolber T, Fauchere I, Haegeli L, On C, Steffel J, and Duru. F. (2012) RFID gates at ski resorts-Is there a risk for patients with ICDs? European Heart Journal 33:993. Notes: Title/abstract: Excluded. Wrong study type.

Woo GW, Petersen SS, Johnson JW, Conti JB, Aranda JA, and Curtis AB. (2005) Ventricular reverse remodeling and 6-month outcomes in patients receiving cardiac resynchronization therapy: analysis of the MIRACLE study. Journal of interventional. cardiac. electrophysiology. : an. international. journal of arrhythmias. and pacing 12:107-113. Notes: Title/abstract: Excluded. Wrong intervention.

Yamokoski LM, Haas GJ, Gans B, and Abraham WT. (2007) OptiVol(registered trademark) fluid status monitoring with an implantable cardiac device: A heart failure management system. Expert Review of Medical Devices 4:775-780. Notes: Title/abstract: Excluded. Wrong study type

Yamokoski LM, Haas GJ, Gans B, and Abraham WT. (2007) OptiVol fluid status monitoring with an implantable cardiac device: a heart failure management system. Expert Review of Medical Devices 4:775-780. Notes: Title/abstract: Excluded. Wrong study type

Yancy CW. (2005) Comprehensive treatment of heart failure: State-of-the-art medical therapy. Reviews in Cardiovascular Medicine 6:S43-S57. Notes: Title/abstract: Excluded. Wrong study type.

Yarnoz MJ and Curtis AB. (2006) Sex-based differences in cardiac resynchronization therapy and implantable cardioverter defibrillator therapies: Effectiveness and use. Cardiology in Review 14:292-298. Notes: Title/abstract: Excluded. Wrong study type

Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, and Wheelan K. (2003) Combined Cardiac Resynchronization and Implantable Cardioversion Defibrillation in Advanced Chronic Heart Failure: The MIRACLE ICD Trial. Journal of the American Medical Association 289:2685-2694. Notes: Title/abstract: Excluded. Wrong indication.

Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, and Wheelan K. (2003) Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: the MIRACLE ICD Trial. JAMA : the. journal of the. American. Medical. Association. 289:2685-2694. Notes: Duplicate

Young JB. (2004) Management of chronic heart failure: What do recent clinical trials teach us? Reviews in Cardiovascular Medicine 5:S3-S9. Notes: Title/abstract: Excluded. Wrong study type

Yung LTM, Wilson S, Johnston RT, and Slade AKB. (2011) Complex cardiac device implantation in a large district general hospital: Can it be done well? Europace 13:iv15. Notes: Title/abstract: Excluded. Wrong study type.

Zabel M, Vollmann D, Luthje L, Seegers J, Sohns C, Zenker D, and Hasenfuss G. (2013) Randomized Clinical evaluatiON of wireless fluid monitoriNg and rEmote ICD managemenT using OptiVol alert-based predefined management to reduce cardiac decompensation and health care utilization: The CONNECT-OptiVol study. Contemporary Clinical Trials 34:109-116. Notes: Title/abstract: Excluded. Wrong intervention.

Zaeem F, Giedriemiene D, Coleman C, Crespo E, Radojevic J, Zweibel S, Kluger J, and Clyne CA. (2012) CRT-D therapy in patients with decompensated NYHA class-four CHF. Cardiology Research and Practice 1. Notes: Title/abstract: Excluded. Wrong study type

Zagrodzky JD, Ramaswamy K, Page RL, Joglar JA, Sheehan CJ, Smith ML, and Hamdan MH. (2001) Biventricular pacing decreases the inducibility of ventricular tachycardia in patients with ischemic cardiomyopathy. American Journal of Cardiology 87:1208-1210. Notes: Title/abstract: Excluded. Wrong study type.

Zareba W and Zareba KM. (2010) Which patients with chronic heart failure should be referred for CRT-D implantation? Practical implications of current clinical research. Polskie Archiwum Medycyny Wewnetrznej 120:95-102. Notes: Title/abstract: Excluded. Wrong study type

Zareba W. (2010) Comparison of clinical trials evaluating cardiac resynchronization therapy in mild to moderate heart failure. Cardiology Journal 17:543-548. Notes: Title/abstract: Included. Full text: Included. SR

Zareba W, Klein H, Cygankiewicz I, Hall WJ, McNitt S, Brown M, Cannom D, Daubert JP, Eldar M, Gold MR, Goldberger JJ, Goldenberg I, Lichstein E, Pitschner H, Rashtian M, Solomon S, Viskin S, Wang P, and Moss AJ. (2011) Effectiveness of cardiac resynchronization therapy by QRS morphology in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT). Circulation 123:1061-1072. Notes: Duplicate

Zareba W, Klein H, Cygankiewicz I, Hall WJ, McNitt S, Brown M, Cannom D, Daubert JP, Eldar M, Gold MR, Goldberger JJ, Goldenberg I, Lichstein E, Pitschner H, Rashtian M, Solomon S, Viskin S, Wang P, and Moss AJ. (2011) Effectiveness of Cardiac Resynchronization Therapy by QRS Morphology in the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT). Circulation 123:1061-1072. Notes: Title/abstract: Included. Full text: Included. MADIT-CRT

Zazzalli K, Corbisiero R, and Muller D. (2010) Pro-arrhythmic or anti-arrhythmic: The role of multi-site left ventricular pacing in heart failure. Journal of Cardiac Failure 16:S62. Notes: Title/abstract: Excluded. Wrong study type.

Zenker D, Murgatroyd F, Burri H, Gjestvang FT, Schwab J, Janko S, and Katz A. (2009) How does complete capture management contribute to the effectiveness of cardiac resynchronization in HF patients? Journal of Cardiac Failure 15:S67. Notes: Title/abstract: Excluded. Wrong study type.

Ziegler P, Koehler JL, and Verma A. (2011) Continuous vs. intermittent monitoring of ventricular rate in patients with permanent atrial fibrillation: All af is not the same. Heart Rhythm 8:S155-S156. Notes: Title/abstract: Excluded. Wrong study type.

Ziegler PD, Koehler JL, and Verma A. (2012) Continuous versus Intermittent Monitoring of Ventricular Rate in Patients with Permanent Atrial Fibrillation. PACE - Pacing and Clinical Electrophysiology 35:598-604. Notes: Title/abstract: Excluded. Wrong study type.

Zizek D, Cvijic M, Tasic J, Jan M, Frljak S, and Zupan I. (2012) Effect of cardiac resynchronization therapy on beat-to-beat T-wave amplitude variability. Europace 14:1646-1652. Notes: Title/abstract: Excluded. Wrong study type.

Zuccaro LM, Rebecchi M, Sciarra L, De Luca L, De Ruvo E, Guarracini F, Mattioli L, Sforza M, and Calo L. (2011) Latitude patient management system: A useful tool in the management of heart failure patients with cardiac resynchronization therapy defibrillator device. Giornale Italiano di Cardiologia 12:158S. Notes: Title/abstract: Excluded. Wrong study type.

(2001) Cardial resynchronisation therapy - CRT (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2001) Atrio-biventricular pacing in severe heart failure - horizon scanning review (Structured abstract). Health Technology Assessment. Database.5. Notes: Title/abstract: Excluded. Wrong study type.

(2005) Implantable cardioverter-defibrillators for the primary prevention of sudden cardiac death due to ventricular arrhythmias (Structured abstract). Health Technology Assessment. Database.24. Notes: Title/abstract: Excluded. Wrong study type.

(2005) Cardiac resynchronization therapy: multi-site pacemaker use (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2005) The use of cardiac resynchronization therapy (CRT) for heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2006) Implantable cardioverter defibrillators for prevention of sudden cardiac death (Structured abstract). Health Technology Assessment. Database.264. Notes: Title/abstract: Excluded. Wrong study type.

(2009) Abstracts - Belgian Society of Cardiology Belgian Heart Rhythm Association, BeHRA: The 3rd Belgian Heart Rhythm Meeting 'Arrhythmias for Every Cardiologist'. Acta Cardiologica 64. Notes: Title/abstract: Excluded. Wrong study type.

(2009) Cardiac resynchronization therapy for mild congestive heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2012) British Cardiovascular Society Annual Conference 2012. Heart 98. Notes: Title/abstract: Excluded. Wrong study type.

(2012) Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120) (Project record). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

Literature search update: 30 April 2013

Barbhaiya C, Po JRF, Hanon S, and Schweitzer P. (2013) Tpeak-Tend and Tpeak-Tend/QT ratio as markers of ventricular arrhythmia risk in cardiac resynchronization therapy patients. PACE - Pacing and Clinical Electrophysiology 36:103-108. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2013) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. International Journal of Cardiology 163:309-315. Notes: Title/abstract: Excluded. Wrong study type.

Botto GL, Dicandia CD, Mantica M, Rosa CL, D'Onofrio A, Bongiorni MG, Molon G, Verlato R, Villani GQ, Scaccia A, Raciti G, and Occhetta E. (2013) Clinical characteristics, mortality, cardiac hospitalization, and ventricular arrhythmias in patients undergoing CRT-D implantation: Results of the ACTION-HF study. Journal of Cardiovascular Electrophysiology 24:173-181. Notes: Title/abstract: Excluded. Wrong study type.

British Cardiovascular Society Annual Conference 2012. Heart 98. Notes: Title/abstract: Excluded. Wrong study type.

Cortes M, Avila P, De La Cruz E, Hernandez JJ, Hernandez I, Navas MA, Benezet-Mazuecos J, Rubio JM, Rabago R, Rey M, Martinez ME, Orejas M, and Farre J. (2013) Usefulness of implantable cardioverter defibrillator therapy in patients aged over 75 years as compared with optimised medical therapy. Journal of the American College of Cardiology 61:E398. Notes: Title/abstract: Excluded. Wrong study type.

Habibovic M, Pedersen SS, Van Den Broek KC, Theuns DAMJ, Jordaens L, Van Der Voort PH, Alings M, and Denollet J. (2013) Anxiety and risk of ventricular arrhythmias or mortality in patients with an implantable cardioverter defibrillator. Psychosomatic Medicine 75:36-41. Notes: Title/abstract: Excluded. Wrong study type.

Haddad H, Dwivedi G, Haddad T, Abo-Shasha R, Mcardle B, Wells RG, Dowsley T, Mielniczuk L, Ruddy T, Beanlands R, Green M, and Chow B. (2013) The effect of CRT therapy on RV function in patients with severe LV dysfunction: A matched control study. Journal of the American College of Cardiology 61:E649. Notes: Title/abstract: Excluded. Wrong study type.

Heidenreich PA, Tsai V, Bao H, Curtis J, Goldstein M, Curtis L, Hernandez A, Peterson P, and Masoudi F. (2013) Cardiac resynchronization therapy in the elderly. Journal of the American College of Cardiology 61:E1477. Notes: Title/abstract: Excluded. Wrong study type.

Kuperstein R, Goldenberg I, Moss A, Solomon S, McNitt S, and Klempfner R. (2013) Left atrial volume and the benefit of cardiac resynchronization therapy in MADIT-CRT. Journal of the American College of Cardiology 61:E572. Notes: Title/abstract: Excluded. Wrong study type.

Kutyifa V, Pouleur AC, Knappe D, Al-Ahmad A, Gibinski M, Wang PJ, McNitt S, Merkely B, Goldenberg I, Solomon SD, Moss AJ, and Zareba W. (2013) Dyssynchrony and the risk of ventricular arrhythmias. JACC: Cardiovascular Imaging 6:432-444. Notes: Title/abstract: Included. MADIT-CRT

Kutyifa V, Kloppe A, Zareba W, Solomon SD, McNitt S, Polonsky S, Barsheshet A, Merkely B, Lemke B, Nagy VK, Moss AJ, and Goldenberg I. (2013) The influence of left ventricular ejection fraction on the effectiveness of cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). Journal of the American College of Cardiology 61:936-944. Notes: Title/abstract: Included. MADIT-CRT

Kutyifa V, Zareba W, McNitt S, Singh J, Hall WJ, Polonsky S, Goldenberg I, Huang DT, Merkely B, Wang PJ, Moss AJ, and Klein H. (2013) Left ventricular lead location and the risk of ventricular arrhythmias in the MADIT-CRT trial. European Heart Journal 34:184-190. Notes: Duplicate

Loring Z, Strauss DG, Gerstenblith G, Tomaselli GF, Weiss RG, and Wu KC. (2013) Cardiac MRI scar patterns differ by sex in an implantable cardioverter-defibrillator and cardiac resynchronization therapy cohort. Heart Rhythm. Notes: Title/abstract: Excluded. Wrong study type.

Mezenski P, Galecki J, Zawadzka A, Bulski W, and Kukolowicz P. (2012) Comparison of 3D-CRT and IMRT techniques in the radiotherapy of breast cancer patients after breast sparing surgery with and without the lymph nodes involvment. Nowotwory 62:423-430. Notes: Title/abstract: Excluded. Wrong study type.

Miranda RI, Nault M, Johri A, Simpson CS, Michael KA, Abdollah H, Baranchuk A, and Redfearn DP. (2012) Maximal electric separation-guided placement of right ventricular lead improves responders in cardiac resynchronization defibrillator therapy. Circulation: Arrhythmia and Electrophysiology 5:927-932. Notes: Title/abstract: Excluded. Wrong study type.

Noyes K, Veazie P, Hall WJ, Zhao H, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2013) Cost-effectiveness of cardiac resynchronization therapy in the MADIT-CRT trial. Journal of Cardiovascular Electrophysiology 24:66-74. Notes: Title/abstract: Included. MADIT-CRT

Ohlow MA, Lauer B, Brunelli M, and Christoph Geller J. (2013) Incidence and predictors of pericardial effusion after permanent heart rhythm device implantation - Prospective evaluation of 968 consecutive patients -. Circulation Journal 77:975-981. Notes: Title/abstract: Excluded. Wrong study type.

Olowokure OO, Bedoya ID, Mierzwa ML, Torregroza MP, Dwivedi AK, Wang J, Smith MT, Schmulewitz N, Kucera S, Choe KA, Ristagno R, Rudich S, Sussman JJ, and Ahmad SA. (2012) Gemcitabine (G) plus nab-paclitaxel (nab-P) plus chemoradiation (CRT) in locally advanced pancreatic cancer (LAPC). Journal of Clinical Oncology 30. Notes: Title/abstract: Excluded. Wrong study type.

Oto A, Aytemir K, Canpolat U, Yorgun H, Kaya EB, Sahiner L, Asil S, Yalcnullin U, Dural M, Sunman H, Kabakcnulli G, and Tokgozonulllu L. (2013) Current practice and applications of transvenous lead extraction using evolution(registered trademark) mechanical dilator sheath. International Journal of Cardiology 163:S48-S49. Notes: Title/abstract: Excluded. Wrong study type.

Pugliese M, Minardi G, Vitali A, Natale E, de Girolamo P, Zampi G, Leggio M, Chiarelli A, Pappalardo A, Avella A, Laurenzi F, and Fera MS. (2012) Influence of myocardial viability on responsiveness to cardiac resynchronization in ischemic dilated cardiomyopathy: A prospective observational cohort study. Anadolu Kardiyoloji Dergisi 12:132-141. Notes: Title/abstract: Excluded. Wrong study type.

Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, Kapa S, Kremers MS, Lindsay BD, and Stevenson LW. (2013) 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force,Heart Rhythm Society. Heart Rhythm 10:e11-e58. Notes: Title/abstract: Excluded. Wrong study type.

Ruwald MH, Ruwald ACH, Jons C, Alexis J, McNitt S, Zareba W, and Moss AJ. (2013) Effect of metoprolol versus carvedilol on outcomes in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). Journal of the American College of Cardiology 61:1518-1526. Notes: Title/abstract: Included. MADIT-CRT

Samii SM and Banchs JE. (2012) Implantable cardiac devices in the treatment of arrhythmias and congestive heart failure. US Cardiology 9:99-104. Notes: Title/abstract: Excluded. Wrong study type.

Sohaib SMA, Chen Z, Whinnett Z, Francis DP, and Manisty C. (2012) Unbiased assessment of symptomatic nullresponse ratenull to cardiac resynchronisation therapy by systematic review of randomised controlled trials (REVERSE, MIRACLE, MIRACLE ICD, MIRACLE ICD II, CARE-HF, COMPANION, CONTAK-CD, and MUSTIC). Heart 98:A1. Notes: Title/abstract: Excluded. Wrong study type.

Sosnowska-Pasiarska B, Bartkowiak R, WoZakowska-Kaplon B, Opolski G, Ponikowski P, Polonski L, Szelemej R, Juszczyk Z, Mirek-Bryniarska E, and DroZdZ J. (2013) Population of Polish patients participating in the Heart Failure Pilot Survey (ESC-HF Pilot). Kardiologia Polska 71:234-240. Notes: Title/abstract: Excluded. Wrong study type.

Tomassoni G, Baker J, Corbisiero R, Love C, Martin D, Niazi I, Sheppard R, Worley S, Beau S, Greer GS, Aryana A, Cao M, Harbert N, and Zhang S. (2013) Postoperative performance of the quartet(registered trademark) left ventricular heart lead. Journal of Cardiovascular Electrophysiology 24:449-456. Notes: Title/abstract: Excluded. Wrong study type.

Tu RH, Peng RL, Zhong GQ, Wu WF, Chen L, and Liang YY. (2013) A systematic review and meta-analysis on efficacy and safety of cardiac resynchronization therapy alone or in combination with implantable cardioversion defibrillation in patients with mild to severe heart failure. Chinese Journal of Cardiology 41:161-170. Notes: Title/abstract: Excluded. Not in English.

Tung P and Albert CM. (2013) Causes and prevention of sudden cardiac death in the elderly. Nature Reviews Cardiology. Notes: Title/abstract: Excluded. Wrong study type.

Verbrugge FH, De Vusser P, Rivero-Ayerza M, Van Herendael H, Rondelez K, Dupont M, Vrolix M, Van Kerrebroeck C, Verhaert D, Vandervoort P, and Mullens W. (2013) Cardiac resynchronization therapy with or without defibrillator: experience from a high-volume Belgian implantation centre. Acta cardiologica 68:37-45. Notes: Title/abstract: Excluded. Wrong study type.

Wasmer K, Kobe J, Andresen D, Zahn R, Spitzer SG, Jehle J, Brachmann J, Stellbrink C, Martens E, Hochadel M, Senges J, Klein H, and Eckardt L. (2013) Comparing outcome of patients with coronary artery disease and dilated cardiomyopathy in ICD and CRT recipients: data from the German DEVICE-registry. Clinical Research in Cardiology1-9. Notes: Title/abstract: Excluded. Wrong study type.

Zabarovskaja S, Gadler F, Gabrielsen A, Hagerman I, Hellgren L, Tornqvist A, Linde C, and Lund LH. (2013) Screening patients with cardiac resynchronization therapy/implantable cardioverter-defibrillator for indications for heart transplantation and left ventricular assist device: A pilot study. Journal of Heart and Lung Transplantation 32:S161. Notes: Title/abstract: Excluded. Wrong study type.

LITERATURE SEARCH FOR ECONOMIC MODELS

Literature search date: 30 April 2013

Aidelsburger P, Grabein K, Klauss V, and Wasem J. (2008) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator (CRT-D) for the treatment of chronic heart failure from a German health care systemperspective. Clinical Research in Cardiology 97:89-97. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Aidelsburger P, Grabein K, Klauss V, and Wasem J. (2008) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator (CRT-D) for the treatment of chronic heart failure from a German health care system perspective (Structured abstract). Clinical. Research. in Cardiology 97:89-97. Notes: Duplicate

Al-Khatib SM, Mi X, Quails L, Frazier-Mills C, Setoguchi-Iwata S, Hess P, and Curtis L. (2012) Follow-up of patients with new cardiovascular implantable electronic devices: Are the experts' recommendations being implemented in routine clinical practice? Heart Rhythm 9:S381. Notes: Title/abstract: Excluded. Wrong study type.

Alaeddini J, Wood MA, Amin MS, and Ellenbogen KA. (2008) Gender disparity in the use of cardiac resynchronization therapy in the United States. PACE - Pacing and Clinical Electrophysiology 31:468-472. Notes: Title/abstract: Excluded. Wrong study type.

Albert NM, Fonarow GC, Yancy CW, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride M, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2010) Outpatient Cardiology Practices With Advanced Practice Nurses and Physician Assistants Provide Similar Delivery of Recommended Therapies (Findings from IMPROVE HF). American Journal of Cardiology 105:1773-1779. Notes: Title/abstract: Excluded. Wrong study type.

Allen LaPointe NM, Al-Khatib SM, Piccini JP, Atwater BD, Honeycutt E, Thomas K, Shah BR, Zimmer LO, Sanders G, and Peterson ED. (2011) Extent of and reasons for nonuse of implantable cardioverter defibrillator devices in clinical practice among eligible patients with left ventricular systolic dysfunction. Circulation: Cardiovascular Quality and Outcomes 4:146-151. Notes: Title/abstract: Excluded. Wrong study type.

Aronow WS. (2008) A focus on when and when not to use antiarrhythmic drugs in treating ventricular arrhythmias and indications for the use of automatic implantable cardioverter-defibrillators. Geriatrics 63:20-28. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Fantoni C. (2004) Cardiac resynchronization therapy in heart failure: Which type and for whom? Dialogues in Cardiovascular Medicine 9:225-231. Notes: Title/abstract: Excluded. Wrong study type.

Auricchio A and Abraham WT. (2004) Cardiac Resynchronization Therapy: Current State of the Art. Cost Versus Benefit. Circulation 109:300-307. Notes: Title/abstract: Excluded. Wrong study type.

Banz K. (2005) Cardiac resynchronization therapy (CRT) in heart failure: a model to assess the economic value of this new medical technology (Structured abstract). Value. in Health 8:128-139. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Barnett D, Phillips S, and Longson C. (2007) Cardiac resynchronisation therapy for the treatment of heart failure: NICE technology appraisal guidance. Heart 93:1134-1135. Notes: Title/abstract: Excluded. Wrong study type.

Bax JJ, Abraham T, Barold SS, Breithardt OA, Fung JWH, Garrigue S, Gorcsan III J, Hayes DL, Kass DA, Knuuti J, Leclercq C, Linde C, Mark DB, Monaghan MJ, Nihoyannopoulos P, Schalij MJ, Stellbrink C, and Yu CM. (2005) Cardiac resynchronization therapy: Part 2 - Issues during and after device implantation and unresolved questions. Journal of the American College of Cardiology 46:2168-2182. Notes: Title/abstract: Excluded. Wrong study type.

Behan MWH and Rinaldi CA. (2006) Cardiac resynchronisation therapy for heart failure. International Journal of Clinical Practice 60:1107-1114. Notes: Title/abstract: Excluded. Wrong study type.

Bentkover JD, Dorian P, Thibault B, and Gardner M. (2007) Economic analysis of a randomized trial of biventricular pacing in Canada. PACE - Pacing and Clinical Electrophysiology 30:38-43. Notes: Title/abstract: Excluded. Wrong study type.

Bernard ML, Quin EM, and Gold MR. (2009) Remote Monitoring-The Future of Implantable Cardioverter-Defibrillator Follow-up. Cardiac Electrophysiology Clinics 1:193-200. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Bernard ML and Gold MR. (2011) Economic Implications and Cost-effectiveness of Implantable Cardioverter Defibrillator and Cardiac Resynchronization Therapy. Heart Failure Clinics 7:241-250. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. Europace 13. Notes: Title/abstract: Excluded. Conference abstract.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2013) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. International Journal of Cardiology 163:309-315. Notes: Title/abstract: Included. Full text: INCLUDE

Betts TR, Jones MA, Wong KCK, Qureshi N, Rajappan K, and Bashir Y. (2011) Cost effectiveness of using a plugged LV Port in ICD recipients with low EF, dyssynchrony mild heart failure symptoms. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Biffi M, Ziacchi M, Bertini M, Sangiorgi D, Corsini D, Martignani C, Diemberger I, and Boriani G. (2008) Longevity of implantable cardioverter-defibrillators: Implications for clinical practice and health care systems. Europace 10:1288-1295. Notes: Title/abstract: Excluded. Wrong study type.

Biffi M, Bertini M, Ziacchi M, Moschini C, Maztotti A, Mantovani V, Gardini B, Cervi E, Martignani C, Diembtrger I, Vaizanta C, Domenickini G, and Boriani G. (2010) Health economy: The true cost oe ICDs as based on their longevity in the real-life scenario. Europace 12:i100. Notes: Title/abstract: Excluded. Wrong study type.

Bilchick KC, Kamath S, Dimarco JP, and Stukenborg GJ. (2010) Bundle-branch block morphology and other predictors of outcome after cardiac resynchronization therapy in medicare patients. Circulation 122:2022-2030. Notes: Title/abstract: Excluded. Wrong study type.

Bilchick KC, Kamath S, Dimarco JP, and Stukenborg GJ. (2010) Bundle-branch block morphology and other predictors of outcome after cardiac resynchronization therapy in medicare patients. Revista Portuguesa de Cardiologia 29:1643-1645. Notes: Title/abstract: Excluded. Wrong study type.

Bilchick KC, Cheng A, Kamath S, and Stukenborg G. (2011) Predictors of outcomes in medicare patients with implantable cardioverter defibrillators. Heart Rhythm 8:S56-S57. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Blecker S and Brancati F. (2011) Comorbid diabetes and expenditures among medicare beneficiaries with heart failure. Journal of General Internal Medicine 26:S192. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Bond M, Mealing S, Anderson R, Dean J, Stein K, and Taylor RS. (2009) Is combined resynchronisation and implantable defibrillator therapy a cost-effective option for left ventricular dysfunction? International Journal of Cardiology 137:206-215. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Bond M, Mealing S, Anderson R, Dean J, Stein K, and Taylor RS. (2009) Is combined resynchronisation and implantable defibrillator therapy a cost-effective option for left ventricular dysfunction? (Structured abstract). International. Journal of Cardiology 137:206-215. Notes: Duplicate

Boriani G, Biffi M, Martignani C, Camanini C, Grigioni F, Rapezzi C, and Branzi A. (2003) Cardioverter-defibrillators after MADIT-II: The balance between weight of evidence and treatment costs. European Journal of Heart Failure 5:419-425. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Biffi M, Martignani C, Valzania C, Diemberger I, Bertini M, Domenichini G, Ziacchi M, and Branzi A. (2009) Is cardiac resynchronization therapy cost-effective? Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 11 Suppl 5:v93-v97. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Boriani G, Mantovani LG, Biffi M, Schalij MJ, Martignani C, Leclercq C, Bax JJ, and Auricchio A. (2011) Cardiac resynchronization therapy: A cost or an investment? Europace 13:ii32-ii38. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Braun MU, Schnabel A, Rauwolf T, Schulze M, and Strasser RH. (2005) Impedance cardiography as a noninvasive technique for atrioventricular interval optimization in cardiac resynchronization therapy. Journal of Interventional Cardiac Electrophysiology 13:223-229. Notes: Title/abstract: Excluded. Wrong study type.

Braunschweig F. (2007) Therapeutic and diagnostic role of electrical devices in acute heart failure. Heart Failure Reviews 12:157-166. Notes: Title/abstract: Excluded. Wrong study type.

Brophy JM. (2008) Resource allocation among cardiovascular specialists and trainees: A pilot survey. Canadian Journal of Cardiology 24:118-120. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Bruggenjurgen B, Israel CW, Klesius AA, Ezzat N, and Willich SN. (2012) Health services research in heart failure patients treated with a remote monitoring device in Germanya retrospective database analysis in evaluating resource use. Journal of Medical Economics 15:737-745. Notes: Title/abstract: Excluded. Wrong study type.

Budde T. (2006) AICD treatment in 2004 - State of the art. European Journal of Medical Research 11:432-438. Notes: Title/abstract: Excluded. Wrong study type.

Burri H, Quesada A, Ricci RP, Boriani G, Davinelli M, Favale S, Da Costa A, Kautzner J, Moser R, Navarro X, and Santini M. (2010) The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) study: Rationale and design. American Heart Journal 160:42-48. Notes: Title/abstract: Excluded. Wrong study type.

Callejo D, Guerra M, Hernandez-Madrid A, and Blasco JA. (2010) Economic assessment of cardiac resynchronization therapy. Revista Espanola de Cardiologia 63:1235-1243. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Callejo D, Martin C, Guerra M, and Blasco JA. (2010) Cardiac resynchronization therapy. Economic evaluation (Structured abstract). Health Technology Assessment. Database. Notes: Duplicate

Calvert MJ, Freemantle N, Yao G, Cleland JG, Billingham L, Daubert JC, and Bryan S. (2005) Cost-effectiveness of cardiac resynchronization therapy: results from the CARE-HF trial (Structured abstract). European. Heart Journal 26:2681-2688. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Camm AJ. (2003) Heart failure and sudden death: Future use of antiarrhythmic drugs and devices. European Heart Journal, Supplement 5:I108-I115. Notes: Title/abstract: Excluded. Wrong study type.

Camm AJ. (2004) Heart failure and sudden death: Future use of antiarrhythmic drugs and devices. European Heart Journal, Supplement 6:I108-I115. Notes: Title/abstract: Excluded. Wrong study type.

Cannizzaro LA, Piccini JP, Patel UD, and Hernandez AF. (2011) Device therapy in heart failure patients with chronic kidney disease. Journal of the American College of Cardiology 58:889-896. Notes: Title/abstract: Excluded. Wrong study type.

Caro JJ, Guo S, Ward A, Chalil S, Malik F, and Leyva F. (2006) Modelling the economic and health consequences of cardiac resynchronization therapy in the UK (Structured abstract). Current. Medical. Research. and Opinion. 22:1171-1179. Notes: : Title/abstract: Included. Full text: Excluded. Wrong indication.

Cevik C, Nugent K, Perez-Verdia A, and Fish RD. (2010) Prophylactic implantation of cardioverter defibrillators in idiopathic nonischemic cardiomyopathy for the primary prevention of death: A narrative review. Clinical Cardiology 33:254-260. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Chen IY and Wu JC. (2011) Cardiovascular molecular imaging: Focus on clinical translation. Circulation 123:425-443. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Crossley G, Boyle A, Vitense H, Sherfesee L, and Mead RH. (2008) Trial design of the clinical evaluation of remote notification to reduce time to clinical decision: The Clinical evaluation Of remote NotificatioN to rEduCe Time to clinical decision (CONNECT) study. American Heart Journal 156:840-846. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Crossley GH, Boyle A, Vitense H, Chang Y, and Mead RH. (2011) The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: The value of wireless remote monitoring with automatic clinician alerts. Journal of the American College of Cardiology 57:1181-1189. Notes: Title/abstract: Excluded. Wrong study type.

Cutro R, Rich MW, and Hauptman PJ. (2012) Device therapy in patients with heart failure and advanced age: Too much too late? International Journal of Cardiology 155:52-55. Notes: Title/abstract: Excluded. Wrong study type.

Czosek RJ, Meganathan K, Anderson JB, Knilans TK, Marino BS, and Heaton PC. (2012) Cardiac rhythm devices in the pediatric population: Utilization and complications. Heart Rhythm 9:199-208. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Das M. (2009) Indications for ICD and cardiac resynchronization therapy for prevention of sudden cardiac death. Expert Review of Cardiovascular Therapy 7:181-195. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JC, Leclercq C, Donal E, and Mabo P. (2006) Cardiac resynchronisation therapy in heart failure: Current status. Heart Failure Reviews 11:147-154. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JC, Leclercq C, and Mabo P. (2009) Cardiac resynchronization therapy in combination with implantable cardioverter-defibrillator. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 11 Suppl 5:v87-v92. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JC, Donal E, and Linde C. (2012) A plea for the wider use of CRT-P in candidates for cardiac resynchronisation therapy. Heart Failure Reviews 17:767-775. Notes: Title/abstract: Excluded. Wrong study type.

de Cock CC, Elders J, van Hemel NM, van den Broek K, van Erven L, de Mol B, Talmon J, Theuns DAMJ, and de Voogt W. (2012) Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands: An expert consensus report of the netherlands society of cardiology. Netherlands Heart Journal 20:53-65. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

De Roy L. (2004) Cardiac rhythm disorders: Problems of the present, challenges for the future. Acta Cardiologica 59:39-41. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Ding L, Hua W, Niu H, Chen K, and Zhang S. (2008) Primary prevention of sudden cardiac death using implantable cardioverter defibrillators. Europace 10:1034-1041. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Dosdall DJ and Ideker RE. (2005) New technologies of internal defibrillation. Journal of Interventional Cardiac Electrophysiology 13:67-70. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Dubner S, Auricchio A, Steinberg JS, Vardas P, Stone P, Brugada J, Piotrowicz R, Hayes DL, Kirchhof P, Breithardt G, Zareba W, Schuger C, Aktas MK, Chudzik M, Mittal S, and Varma N. (2012) ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Annals of Noninvasive Electrocardiology 17:36-56. Notes: Title/abstract: Excluded. Wrong study type.

Ellery S, Williams L, and Frenneaux M. (2006) Role of resynchronisation therapy and implantable cardioverter defibrillators in heart failure. Postgraduate Medical Journal 82:16-23. Notes: Title/abstract: Excluded. Wrong study type.

Epstein AE. (2005) New insights into cardiac resynchronization therapy. Clinical Cardiology 28:I45-I50. Notes: Title/abstract: Excluded. Wrong study type.

Epstein AJ, Polsky D, Yang F, Yang L, and Groeneveld PW. (2012) Geographic variation in implantable cardioverter-defibrillator use and heart failure survival. Medical Care 50:10-17. Notes: Title/abstract: Excluded. Wrong study type.

Ermis C and Benditt DG. (2006) Cardiac resynchronization pacing without defibrillator capability: Is this a viable option? Europace 8:499-501. Notes: Title/abstract: Excluded. Wrong study type.

Fabbri SC, Petersen DK, and Westrom SJ. (2009) Quality improvement assessment in an outpatient heart failure clinic. Heart and Lung: Journal of Acute and Critical Care 38:269. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Farmer SA, Tuohy EJ, Small DS, Wang Y, and Groeneveld PW. (2012) Impact of community wealth on use of cardiac-resynchronization therapy with defibrillators for heart failure patients. Circulation: Cardiovascular Quality and Outcomes 5:798-807. Notes: Title/abstract: Excluded. Wrong study type.

Feldman AM, De Lissovoy G, Bristow MR, Saxon LA, De Marco T, Kass DA, Boehmer J, Singh S, Whellan DJ, Carson P, Boscoe A, Baker TM, and Gunderman MR. (2005) Cost effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial. Journal of the American College of Cardiology 46:2311-2321. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Feldman AM, Lissovoy G, Bristow MR, Saxon LA, Marco T, Kass DA, Boehmer J, Singh S, Whellan DJ, Carson P, Boscoe A, Baker TM, and Gunderman MR. (2005) Cost effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial (Provisional abstract). Journal of the. American. College. of Cardiology 46:2311-2321. Notes: Duplicate

Field ME and Sweeney MO. (2006) Socio-economic analysis of cardiac resynchronization therapy. Journal of Interventional Cardiac Electrophysiology 17:225-236. Notes: Title/abstract: Excluded. Wrong study type.

Fonarow GC. (2005) Strategies to improve the use of evidence-based heart failure therapies. Reviews in Cardiovascular Medicine 6:S32-S42. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Fonarow GC. (2006) How well are chronic heart failure patients being managed? Reviews in Cardiovascular Medicine 7:S3-S11. Notes: Title/abstract: Excluded. Wrong study type.

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: Systematic review and economic model. Health Technology Assessment 11:iii-135. Notes: Duplicate

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model. Health technology assessment (Winchester, England) 11:iii-248. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Freeman JV, Ullal A, and Turakhia MP. (2011) Cost-effectiveness of Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy. Cardiac Electrophysiology Clinics 3:421-440. Notes: Title/abstract: Excluded. Wrong study type.

Frisch AN, Dailey MW, Heeren D, and Stern M. (2009) Precision of time devices used by prehospital providers. Prehospital Emergency Care 13:247-250. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Glatter KA, Young JN, and McElvany MD. (2006) Implantable cardioverter-defibrillators: a new preventive medical option. Preventive cardiology 9:49-53. Notes: Title/abstract: Excluded. Wrong study type.

Goldberger Z and Lampert R. (2006) Implantable cardioverter-defibrillators: Expanding indications and technologies. Journal of the American Medical Association 295:809-818. Notes: Title/abstract: Excluded. Wrong study type.

Goldenberg I and Moss AJ. (2008) Implantable Device Therapy. Progress in Cardiovascular Diseases 50:449-474. Notes: Title/abstract: Excluded. Wrong study type.

Gregoratos G. (2005) Indications and recommendations for pacemaker therapy. American Family Physician 71:1563-1570. Notes: Title/abstract: Excluded. Wrong study type.

Grimm W. (2008) Outcomes of elderly heart failure recipients of ICD and CRT. International Journal of Cardiology 125:154-160. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Haddad M, Lam K, Hendry P, Mesana T, and Davies R. (2005) Left ventricular assist devices for the treamtent of congestive heart failure. Current Treatment Options in Cardiovascular Medicine 7:47-54. Notes: Title/abstract: Excluded. Wrong study type.

Haiyan W, Yusheng X, Qiangsun Z, Yin L, Yanling T, Yi W, Luxing Z, Zhixin J, and Jianbo H. (2009) A portable, economic drainage device to prevent pocket hematoma of pacemakers. Journal of Medical Colleges of PLA 24:167-175. Notes: Title/abstract: Excluded. Wrong study type.

Hasan A and Paul V. (2011) Telemonitoring in chronic heart failure. European Heart Journal 32:1457-1464. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Hauptman PJ, Swindle JP, Masoudi FA, and Burroughs TE. (2010) Underutilization of (beta)-blockers in patients undergoing implantable cardioverter-defibrillator and cardiac resynchronization procedures. Circulation: Cardiovascular Quality and Outcomes 3:204-211. Notes: Title/abstract: Excluded. Wrong study type.

Hazukova R, Praus R, Cermakova E, Furmanova V, Vojacek J, and Pleskot M. (2012) Pharmaco-refractory chronic heart failure - The need for drug level tailored management. Medical Hypotheses 79:560-563. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Hebert K, Mckinnie J, Horswell R, Arcement L, and Stevenson L. (2006) Expansion of Heart Failure Device Therapy Into a Rural Indigent Population in Louisiana: Potential Economic and Health Policy Implications. Journal of Cardiac Failure 12:689-693. Notes: Title/abstract: Excluded. Wrong study type.

Herz ND, Strauss DG, Ritchey ME, Lorin Z, Jacobs SB, Silverma H, Worrall CM, Kelma J, Pina IL, and Canos DA. (2012) Cardiac resynchronization therapy defibrillators: PRE and postmarket experience. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Jego C and Deharo JC. (2004) Implantable defibrillator and ventricular resynchronisation. Archives des Maladies du Coeur et des Vaisseaux 97:1122-1129. Notes: Title/abstract: Excluded. Wrong study type.

Jeilan M, Das D, Tuan JH, Nicolson W, Kundu S, Yusuf S, Osman F, Wong S, Loke I, and Ng GA. (2009) The trade off between device and patient longevity in cost-effective analyses of CRT-D. European Heart Journal 30:1010-1011. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Jessup M. (2003) Resynchronization therapy is an important advance in the management of congestive heart failure: View of an antagonist. Journal of Cardiovascular Electrophysiology 14:S30-S34. Notes: Title/abstract: Excluded. Wrong study type.

Ji SY and Travin MI. (2010) Radionuclide imaging of cardiac autonomic innervation. Journal of Nuclear Cardiology 17:655-666. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

John Camm A and Nisam S. (2010) European utilization of the implantable defibrillator: Has 10 years changed the enigma? Europace 12:1063-1069. Notes: Title/abstract: Excluded. Wrong study type.

Jones MA, Betts TR, Rajappan K, Bashir Y, Wong KCK, and Qureshi N. (2011) Is it cost effective to use a plugged LV port? Heart 97:A88. Notes: Title/abstract: Excluded. Conference abstract.

Jung W, Wolpert C, Esmailzadeh B, Spehl S, Herwig S, Schumacher B, Lewalter T, Omran H, Kirchhoff PG, and Luderitz B. (1998) Specific considerations with the automatic implantable atrial defibrillator. Journal of Cardiovascular Electrophysiology 9:S193-S201. Notes: Title/abstract: Excluded. Wrong study type.

Jung W, Wolpert C, Herwig S, Spehl S, Esmailzadeh B, Schneider C, Schumacher B, Lewalter T, Schimpf R, Omran H, Kirchhoff PG, and Luderitz B. (1998) Initial experience with the implantable atrial and combined atrioventricular defibrillator. Herzschrittmachertherapie und Elektrophysiologie 9:94-101. Notes: Title/abstract: Excluded. Wrong study type.

Jung W, Rillig A, Birkemeyer R, Miljak T, and Meyerfeldt U. (2008) Advances in remote monitoring of implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy systems. Journal of Interventional Cardiac Electrophysiology 23:73-85. Notes: Title/abstract: Excluded. Wrong study type.

Kadish A and Mehra M. (2005) Heart failure devices: Implantable cardioverter-defibrillators and biventricular pacing therapy. Circulation 111:3327-3335. Notes: Title/abstract: Excluded. Wrong study type.

Kadish AH, Reiffel JA, Naccarelli GV, and Dimarco JP. (2008) Device Therapies in the Post-Myocardial Infarction Patient with Left Ventricular Dysfunction. American Journal of Cardiology 102:29G-37G. Notes: Title/abstract: Excluded. Wrong study type.

Kao DP, Raff H, and Peterson P. (2009) Gender differences in use of implantable cardiac defibrillators and resynchronization therapy for heart failure in California, 2000-2006. Journal of Cardiac Failure 15:S79-S80. Notes: Title/abstract: Excluded. Wrong study type.

Katz DF, Pellegrini CN, Heidenreich PA, Keung EC, Peterson P, Rumsfeld JS, Massie BM, and Varosy PD. (2012) Center for medicare and medicaid services reimbursement criteria concordant primary prevention icd implantation in the outcomes among veterans with implantable defibrillators (OVID) registry. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Kazi DS and Mark DB. (2013) The Economics of Heart Failure. Heart Failure Clinics 9:93-106. Notes: Title/abstract: Excluded. Wrong study type.

Kirkpatrick JN and Knight BP. (2008) The management of implantable cardiac devices at the end of life. Progress in Palliative Care 16:250-256. Notes: Title/abstract: Excluded. Wrong study type.

Klein MH and Gold MR. (2008) Use of Traditional and Biventricular Implantable Cardiac Devices for Primary and Secondary Prevention of Sudden Death. Cardiology Clinics 26:419-431. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Krum H and Abraham WT. (2009) Heart failure. The Lancet 373:941-955. Notes: Title/abstract: Excluded. Wrong study type.

Kuo HC, Yang YH, Ho PS, and Chang LT. (2011) Risk of comorbidity on head and neck cancer treatment: A population-based study. Oral Oncology 47:S93. Notes: Title/abstract: Excluded. Wrong study type.

Kusumoto FM and Goldschlager N. (2010) Remote monitoring of patients with implanted cardiac devices. Clinical Cardiology 33:10-17. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Kutyifa V, Aidelsburger P, Schauer S, Merkely B, Klein H, Kuniss M, Kloppe A, Kayser T, Peppa R, and Moss AJ. (2012) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator in mild heart failure based on Markov modeling using UK cost approach in MADIT CRT. European Heart Journal 33:896. Notes: Title/abstract: Excluded. Conference abstract.

Lam SKH, Tse HF, and Lau CP. (2008) CRT begets CRT-D: Is one better than the other? Journal of Cardiovascular Electrophysiology 19:1266-1269. Notes: Title/abstract: Excluded. Wrong study type.

Lanni T, Shah C, Wilkinson JB, Wobb J, Jawad MS, Wallace M, Grills IS, and Chen P. (2012) Comparison of reimbursement and cost efficacy between accelerated partial breast irradiation modalities. International Journal of Radiation Oncology Biology Physics 84:S236. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Lau CP, Tse HF, and Mond HG. (2006) The impact of reimbursement on the usage of pacemakers, implantable cardioverter defibrillators and radiofrequency ablation. Journal of Interventional Cardiac Electrophysiology 17:177-181. Notes: Title/abstract: Excluded. Wrong study type.

Lazarus A, Biondi N, Thebaut JF, Durand-Zaleski I, and Chauvin M. (2011) Implantable cardioverter-defibrillators in France: practices and regional variability. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 13:1568-1573. Notes: Title/abstract: Excluded. Wrong study type.

Leclercq C and Hare JM. (2004) Ventricular Resynchronization: Current State of the Art. Circulation 109:296-299. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Leclercq C, Mabo C, and Daubert JC. (2008) Cardiac resynchronization therapy: Which device to implant? Archives of Cardiovascular Diseases 101:55-60. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Lee MY. (2006) Cardiac resynchronization therapy; biventricular pacing. Korean Circulation Journal 36:329-336. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Lehmann MH and Aaronson KD. (2006) CRT-D therapy in heart failure: How much do NYHA class IV patients benefit? Journal of Cardiovascular Electrophysiology 17:491-494. Notes: Title/abstract: Excluded. Wrong study type.

Linde C, Mealing S, Hawkins N, Eaton J, Brown B, and Daubert JC. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure: insights from the

European cohort of the REVERSE (Resynchronization Reverses remodeling in Systolic Left Ventricular Dysfunction) (Structured abstract). European. Heart Journal 32:1631-1639. Notes: Title/abstract: Included. Full text: INCLUDE

Loring Z, Canos DA, Selzman K, Herz ND, Silverman H, MaCurdy TE, Worrall CM, Kelman J, Richey ME, Pina IL, and Strauss DG. (2012) Left bundle branch block predicts better survival in women than men receiving cardiac resynchronization therapy: Long term follow-up of 145,000 patients. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Luqman N, Wang CL, Sung RJ, and Kuo CT. (2008) Emerging role of cardiac resynchronization therapy in heart failure. Acta Cardiologica Sinica 24:1-14. Notes: Title/abstract: Excluded. Wrong study type.

Machado M, Menezes Falcao L, and Ravara L. (2006) Sudden death prevention in heart failure. Revista Portuguesa de Cardiologia 25:727-762. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Manolis AS. (2004) Cardiac resynchronization therapy in congestive heart failure: Ready for prime time? Heart Rhythm 1:355-363. Notes: Title/abstract: Excluded. Wrong study type.

Mant J, Al-Mohammad A, Swain S, and Laramee P. (2011) Management of chronic heart failure in adults: Synopsis of the National Institute for Health and Clinical Excellence guideline. Annals of Internal Medicine 155:252-259. Notes: Title/abstract: Excluded. Wrong study type.

Marchel M, Filipiak KJ, and Steckiewicz R. (2003) Cardiac resynchronization therapy in congestive heart failure. Polski Przeglad Kardiologiczny 5:91-95. Notes: Title/abstract: Excluded. Wrong study type.

Mariani JA, Gould PA, Broughton A, and Kaye DM. (2006) Cardiac resynchronisation therapy for heart failure. Internal Medicine Journal 36:114-123. Notes: Title/abstract: Excluded. Wrong study type.

Masella C, Zanaboni P, Di Stasi F, Gilardi S, Ponzi P, and Valsecchi S. (2008) Assessment of a remote monitoring system for implantable cardioverter defibrillators. Journal of telemedicine and telecare 14:290-294. Notes: Title/abstract: Excluded. Wrong study type.

McAlister FA, Ezekowitz J, Hooton N, Vandermeer B, Spooner C, Dryden DM, Page RL, Hlatky MA, and Rowe BH. (2007) Cardiac resynchronization therapy for patients with left ventricular systolic dysfunction: A systematic review. Journal of the American Medical Association 297:2502-2514. Notes: Title/abstract: Excluded. Wrong study type.

McAlister FA, Ezekowitz J, Dryden DM, Hooton N, Vandermeer B, Friesen C, Spooner C, and Rowe BH. (2007) Cardiac resynchronization therapy and implantable cardiac defibrillators in left ventricular systolic dysfunction. Evidence report/technology assessment1-199. Notes: Title/abstract: Excluded. Wrong study type.

McAlister FA, Ezekowitz J, Dryden DM, Hooton N, Vandermeer B, Friesen C, Spooner C, and Rowe BH. (2007) Cardiac resynchronization therapy and implantable cardiac defibrillators in left ventricular systolic dysfunction (Structured abstract). Health Technology Assessment. Database.199. Notes: Duplicate

Mehra MR, Yancy CW, Albert NM, Curtis AB, Stough WG, Gheorghiade M, Heywood JT, McBride ML, O'Connor CM, Reynolds D, Walsh MN, and Fonarow GC. (2009) Evidence of clinical practice heterogeneity in the use of implantable cardioverter-defibrillators in heart failure and post-myocardial infarction left ventricular dysfunction: Findings from IMPROVE HF. Heart Rhythm 6:1727-1734. Notes: Title/abstract: Excluded. Wrong study type.

Mehra R, Dasgupta S, and Radhakrishnan R. (2011) Optimal use of defibrillators and CRT in India--awareness, guidelines and finances: the industry view point. Indian heart journal 63:351-355. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Mele D, Toselli T, Pratola C, Artale P, and Ferrari R. (2007) Cardiac resynchronization therapy and mortality reduction in heart failure: A proven association. Giornale Italiano di Cardiologia 8:760-769. Notes: Title/abstract: Excluded. Wrong study type.

Merchant K and LaBorde A. (2005) Implementing a cardiac resynchronization therapy program in a county hospital. Journal of Nursing Administration 35:404-409. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B. (2005) Treatment with pacemaker and implantable cardioverter defibrillators - New results. Orvosi Hetilap 146:1088-1098. Notes: Title/abstract: Excluded. Wrong study type.

Merkely B, Roka A, Kutyifa V, Boersma L, Leenhardt A, Lubinski A, Oto A, Proclemer A, Brugada J, Vardas PE, and Wolpert C. (2010) Tracing the European course of cardiac resynchronization therapy from 2006 to 2008. Europace 12:692-701. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Morgan JM, Gill J, Ng A, McComb J, Roderick P, Seed A, Williams S, Witte K, Wright D, and Cowie M. (2012) Economic analysis of a feasibility study of remote monitoring in heart failure (REM-HF-F). Europace 14:iv16. Notes: Title/abstract: Excluded. Conference abstract.

Mostov S, Haim M, Nevzorov R, Hasadi D, Starsberg B, and Porter A. (2011) Prognosis of heart failure patients undergoing implantation of biventricular pacemaker with and without a defibrillator. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Munjal J, Waqar F, Jamali H, Gujja P, Muth J, Costea A, Almuti K, and Attari M. (2012) Is interrogation of implantable devices necessary at 1 week follow up? A study in health care cost. Heart Rhythm 9:S49. Notes: Title/abstract: Excluded. Wrong study type.

Naccarelli GV. (2005) Post myocardial infarction, left ventricular dysfunction, and the expanding role of cardiac implantable electrical devices. Clinical Cardiology 28:I51-I57. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Narayan SM. (2005) Implantable defibrillators with and without resynchronization for patients with left ventricular dysfunction. Texas Heart Institute Journal 32:358-361. Notes: Title/abstract: Excluded. Wrong study type.

Neuzner J, Willems S, Klein HU, and Block M. (2010) Chance for young electrophysiologists: The continuing education program "fellowship heart rhythm". Herzschrittmachertherapie und Elektrophysiologie 21:186-188. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Neyt M, Stroobandt S, Obyn C, Camberlin C, Devriese S, De Laet C, and Van Brabandt H. (2011) Cost-effectiveness of cardiac resynchronisation therapy for patients with moderate-to-severe heart failure. Value in Health 14:A253. Notes: Title/abstract: Excluded. Conference abstract.

Nichol G, Kaul P, Huszti E, and Bridges J-FP. (2004) Cost-effectiveness of cardiac resynchronization therapy in patients with symptomatic heart failure (Structured abstract). Annals. of Internal. Medicine 141:343-351. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Noyes K, Veazie P, Hall WJ, Zhao H, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2013) Cost-effectiveness of cardiac resynchronization therapy in the MADIT-CRT trial. Journal of Cardiovascular Electrophysiology 24:66-74. Notes: Title/abstract: Included. Full text: INCLUDE

Oliveira M, Silva Cunha P, and da Silva N. (2013) Remote monitoring for follow-up of patients with implantable cardiac devices. Revista Portuguesa de Cardiologia. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Ondrackova B, Miklik R, Parenica J, Spinar J, Sticha M, and Sulcova A. (2009) In hospital costs of acute heart failure patients in the Czech Republic. Central European Journal of Medicine 4:483-489. Notes: Title/abstract: Excluded. Wrong study type.

Ondrackova B, Parenica J, Felsoci M, Miklik R, Horakova K, Spinar J, and Sulcova A. (2010) Cost comparison study in acute coronary syndromes and acute heart failure patients. Value in Health 13:A348. Notes: Title/abstract: Excluded. Wrong study type.

Osmera O and Bulava A. (2010) Telemedicine - A discovery of the third millennium? Cor et Vasa 52:55-61. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Park KW. (2012) Nonsurgical therapy for heart failure. International Anesthesiology Clinics 50:1-21. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Pavia SV and Wilkoff BL. (2001) Biventricular pacing for heart failure. Cardiology Clinics 19:637-651. Notes: Title/abstract: Excluded. Wrong study type.

Peterzan M, Timmis A, Moffat D, Davies C, Mohiddin SA, Mathur A, Knight C, Westwood MA, and Sekhri N. (2013) A retrospective audit of whether patients undergoing myocardial perfusion scintigraphy (MPS) are suitable for Stress cardiac magnetic resonance imaging (CMR). Journal of Cardiovascular Magnetic Resonance 15:58. Notes: Title/abstract: Excluded. Wrong study type.

Piccini JP and Hranitzky P. (2007) Diagnostic monitoring strategies in heart failure management. American Heart Journal 153:12-17. Notes: Title/abstract: Excluded. Wrong study type.

Porter A, Mostov S, Nevzorov R, Kusnies H, Golovciner G, Iakobishvilli Z, Hasdai D, Strasberg B, and Haim M. (2011) Prognosis of heart failure patients undergoing implantation of biventricular pacemaker therapy with or without a defibrillator. European Journal of Heart Failure, Supplement 10:S73. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Ramani GV, Uber PA, and Mehra MR. (2010) Chronic heart failure: Contemporary diagnosis and management. Mayo Clinic Proceedings 85:180-195. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Reynolds MR, Cohen DJ, Kugelmass AD, Brown PP, Becker ER, Culler SD, and Simon AW. (2006) The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators. Journal of the American College of Cardiology 47:2493-2497. Notes: Title/abstract: Excluded. Wrong study type.

Ricci RP, D'Onofrio A, Padeletti L, Sagone A, Vicentini A, Vincenti A, Morichelli L, Cavallaro C, Ricciardi G, Lombardi L, Fusco A, Rovaris G, Silvestri P, Guidotto T, Pollastrelli A, and Santini M. (2012) Rationale and design of the health economics evaluation registry for remote follow-up: TARIFF. Europace 14:1661-1665. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Rigau CD, Sola A, I, Alonso CP, and Martinez PF. (2008) Efficacy of biventricular pacemakers for heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

Rihova B, Parenica J, Miklik R, Felsoci M, Horakova K, Sulcova A, Jarkovsky J, and Spinar J. (2011) Cost of acute heart failure related readmissions. Vnitrni Lekarstvi 57:803-807. Notes: Title/abstract: Excluded. Wrong study type.

Rivera DA and Bristow MR. (2005) Cardiac resynchronization - A heart failure perspective. Annals of Noninvasive Electrocardiology 10:16-23. Notes: Title/abstract: Excluded. Wrong study type.

Ross HM and Kocovic DZ. (2004) Cardiac resynchronization therapy for heart failure. Current Treatment Options in Cardiovascular Medicine 6:365-370. Notes: Title/abstract: Excluded. Wrong study type.

Rudzinski T. (2004) Electrotherapy of congestive heart failure. Polski Przeglad Kardiologiczny 6:453-455. Notes: Title/abstract: Excluded. Wrong study type.

Saberwal B, Ahsan SY, Lambiase PD, Segal OR, Lowe M, Koo C, Gopalamurugan AB, Rowland E, Nunn L, and Chow AWC. (2011) Cost analysis of early cardiac device infections. Europace 13:iv15. Notes: Title/abstract: Excluded. Wrong study type.

Saberwal B, Ahsan SY, Lambiase P, Segal O, Lowe M, Koo C, Nunn L, Gopalamurugan AB, Rowland E, and Chow AWC. (2011) Cost analysis of early cardiac device infections. European Heart Journal 32:674-675. Notes: Title/abstract: Excluded. Wrong study type.

Samii SM and Banchs JE. (2012) Implantable cardiac devices in the treatment of arrhythmias and congestive heart failure. US Cardiology 9:47-52. Notes: Title/abstract: Excluded. Wrong study type.

Sanders GD, Hlatky MA, and Owens DK. (2005) Cost-effectiveness of implantable cardioverter-defibrillators (Structured abstract). New England. Journal of Medicine 353:1471-1480. Notes: Title/abstract: Included. Full text: Excluded. Wrong intervention.

Sauer WH and Bristow MR. (2008) The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial in perspective. Journal of Interventional Cardiac Electrophysiology 21:3-11. Notes: Title/abstract: Excluded. Wrong study type.

Saxon LA and Wilkoff BL. (2012) CRT or CRT-D devices? The case for 'high energy' devices. Heart Failure Reviews 17:777-779. Notes: Title/abstract: Excluded. Wrong study type.

Sedlacek K, Jurkuvenas P, Hoskova L, Malek I, and Kautzner J. (2011) Patterns of ICD use in patients enlisted for heart transplantation: A single centre retrospective analysis 2006-2010. PACE - Pacing and Clinical Electrophysiology 34:1337. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Semeniuk L, Lee H, Manns B, Shibata M, Sondergaard R, Haggard S, Mitchell RT, Cowan K, Giliis AM, Belenkie I, and Exner DV. (2011) Cost comparison in heart failure patients treated with cardiac resynchronization, pacemaker, internal cardiac defibrillation, and standard medical therapies. What is a longer life worth? Heart Rhythm 8:S161. Notes: Title/abstract: Excluded. Wrong study type.

Sethi KK and Dhall A. (2011) Optimal utilization of defibrillators and CRT in India--awareness, guidelines and financing--the cardiologist's viewpoint. Indian heart journal 63:347-350. Notes: Title/abstract: Excluded. Wrong study type.

Shah C, Lanni T, Wilkinson JB, Jawad M, Wobb J, Berry S, Wallace M, Chen P, and Grills IS. (2012) Cost-effectiveness of 3-dimensional conformal radiotherapy and applicator-based brachytherapy in the delivery of accelerated partial breast irradiation. American Journal of Clinical Oncology: Cancer Clin. Notes: Title/abstract: Excluded. Wrong indication.

Shah P, Rongione AJ, Hewitt PD, Rosner CM, May CW, Burton NA, and Desai SS. (2012) Is cardiac resynchronization therapy a cost-effective strategy in patients whose ultimate destination is a left ventricular assist device? Journal of Heart and Lung Transplantation 31:S50-S51. Notes: Title/abstract: Excluded. Conference abstract.

Shimizu A. (2009) Cardiac resynchronization therapy with and without implantable cardioverter-defibrillator. Circulation Journal 73:A29-A35. Notes: Title/abstract: Excluded. Wrong study type.

Silva Melchor L, Garcia-Pavia P, and Aso JO. (2006) Cardiac resynchronization therapy and prevention of sudden cardiac death in heart failure. From clinical trials to clinical practice. Revista Espanola de Cardiologia Suplementos 6:59F-70F. Notes: Title/abstract: Excluded. Wrong study type.

Sinagra G, Perkan A, Cherubini A, Salvatore L, and Di Lenarda A. (2002) Treatment of heart failure: An update. Italian Heart Journal Supplement 3:691-697. Notes: Title/abstract: Excluded. Wrong study type.

Smala A, Gessler M, and Stoepel C. (2011) Societal costs of routine follow-up services for cardiac implantable electrical devices in Germany and the united kingdom - And the impact of remote monitoring. Value in Health 14:A247. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Smala A, Gessler M, and Stoepel C. (2011) Demand for routine in office follow-up visits for cardiac implantable electrical devices (CIED) in Germany and the United Kingdom. Value in Health 14:A256. Notes: Title/abstract: Excluded. Wrong study type.

Smala A and Vogtmann T. (2011) Workload in German hospitals caused by routine follow-up services for cardiac implantable electrical devices (CIED). Value in Health 14:A253. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Smala A, Gessler M, and Vogtmann T. (2011) Resource use caused by in-office follow-up visits for cardiac implantable electrical devices (CIED) in Germany and the United Kingdom. Value in Health 14:A257. Notes: Title/abstract: Excluded. Wrong study type.

Smith T, Bosch JL, Van Domburg RT, Muskens-Heemskerk A, Theuns DA, and Jordaens L. (2009) Contemporary results and health care utilisation after ICD therapy for primary prevention in coronary artery disease and dilated cardiomyopathy. European Heart Journal 30:418. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Smith W. (2010) New Zealand primary implantable cardioverter defibrillator implantation and biventricular pacing guidelines. New Zealand Medical Journal 123:86-96. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Sohail MR, Henrikson CA, Braid-Forbes MJ, Forbes KF, and Lerner DJ. (2011) Mortality and cost associated with cardiovascular implantable electronic device infections. Archives of Internal Medicine 171:1821-1828. Notes: Title/abstract: Excluded. Wrong study type.

Solik P, Varga I, Lesny P, Luknar M, Babej S, Liska B, and Goncnullalvesova E. (2011) Characteristics and outcomes of patients hospitalized for acute heart failure in Slovakia. Cardiology Letters 20:51S. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Stabile G, Iuliano A, Turco P, Ciardiello C, and De Simone A. (2009) Cardiac resynchronization therapy: A review of CRT-D versus CRT-P. Future Cardiology 5:567-572. Notes: Title/abstract: Excluded. Wrong study type.

Steffel J, Holzmeister J, and Abraham WT. (2011) Recent advances in cardiac resynchronization therapy. Postgraduate Medicine 123:18-26. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Sticherling C, Kuhne M, Schaer B, Altmann D, and Osswald S. (2009) Remote monitoring of cardiovascular implantable electronic devices: Prerequisite or luxury? Swiss Medical Weekly 139:596-601. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Sudhakar S, Shivkumar S, Shaloob M, Vishinu R, Arunachalam A, Sitaram S, Shilendra S, and Sai VBK. (2012) Prognosis and prediction of appropriate defibrillator therapy in patients with chronic heart failure. American Journal of Cardiology 109:72S. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Sullivan RM and Olshansky B. (2011) Is a dual-chamber ICD always better in patients requiring an ICD? Cardiac Electrophysiology Clinics 3:577-592. Notes: Title/abstract: Excluded. Wrong study type.

Sweeney MO, Sakaguchi S, Simons G, Machado C, Connett JE, and Yang F. (2012) Response to the Center for Medicare & Medicaid Services coverage with evidence development request for primary prevention implantable cardioverter-defibrillators: Data from the OMNI study. Heart Rhythm 9:1058-1066. Notes: Title/abstract: Excluded. Wrong study type.

Swindle J, Burroughs TE, Schnitzler MA, and Hauptman PJ. (2008) Short-term mortality and cost associated with cardiac device implantation in patients hospitalized with heart failure. American Heart Journal 156:322-328. Notes: Title/abstract: Excluded. Wrong study type.

Swindle JP, Rich MW, McCann P, Burroughs TE, and Hauptman PJ. (2010) Implantable cardiac device procedures in older patients: Use and in-hospital outcomes. Archives of Internal Medicine 170:631-637. Notes: Title/abstract: Excluded. Wrong study type.

Tarab AD, Dougher CE, Rogers TB, Bril SL, Tsintzos S, Goss T, and Veath BK. (2012) Budget impact of selecting cardiac resynchronization therapy (CRT) devices with adaptive (nullACRTnull) programming algorithms under the united states medicare payment setting. Value in Health 15:A349. Notes: Title/abstract: Excluded. Wrong study type.

Tarab AD, Dougher CE, Rogers TB, Bril SL, Tsintzos S, Brown B, Chapman M, Klesius A, Eggleston A, Sadri H, Goss T, and Veath BK. (2012) Financial impact of adaptive cardiac resynchronization therapy (ACRT) device algorithms in the united kigdom, germany, australia and canada: Are there savings associated with device selection? Value in Health 15:A349. Notes: Title/abstract: Excluded. Conference abstract.

Thijssen J, Van Den Akker ME, Borleffs CJW, Van Rees JB, De Bie MK, Van Der Velde ET, van Erven L, and Schalij MJ. (2011) Cost-effectiveness of prophylactic cardioverter defibrillator implantation in a large single center cohort. European Heart Journal 32:312. Notes: Title/abstract: Excluded. Conference abstract.

Tomini F and Van Asselt AD. (2012) A review of economic evaluation models for cardiac resynchronization therapy with implantable cardioverter defibrillators in patients with heart failure. Value in Health 15:A356. Notes: Title/abstract: Excluded. Conference abstract.

Tuppin P, Neumann A, Marijon E, De Peretti C, Weill A, Ricordeau P, Danchin N, and Allemand H. (2011) Implantation and patient profiles for pacemakers and cardioverter- defibrillators in France

(2008-2009). Archives of Cardiovascular Diseases 104:332-342.
Notes: Title/abstract: Excluded. Wrong study type.

Van Gelder IC, Smit MD, Nieuwland W, and Van Veldhuisen DJ. (2006) Non-pharmacological treatment of heart failure: Implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy. Nederlands Tijdschrift voor Geneeskunde 150:2238-2244. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

van Hemel NM. (2007) A review of factors contributing to health related quality of life achieved with cardiac resynchronization therapy for heart failure. Minerva Cardioangiologica 55:783-802. Notes: Title/abstract: Excluded. Wrong study type.

Vardas P and Boriani G. (2011) Health economics and the European Heart Rhythm Association. Europace 13:ii1-ii2. Notes: Title/abstract: Excluded. Wrong study type.

Vaz Carneiro Cembre A. (2008) Drug therapy for chronic heart failure due to left ventricular systolic dysfunction: A scientific review. I. Introduction. Revista Portuguesa de Cardiologia 27:851-856. Notes: Title/abstract: Excluded. Wrong study type.

Viray MA, Liang SY, Warren DK, Gleva MJ, Subramaniam H, Fraser VJ, and Olsen MA. (2012) Increased incidence of infection in cardiac resynchronization devices compared with pacemakers: Insights from a longitudinal medicare population. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Voigt A, Shalaby A, Adelstein E, and Saba S. (2010) Beta-blocker utilization and outcomes in patients receiving cardiac resynchronization therapy. Clinical Cardiology 33:E1-E5. Notes: Title/abstract: Excluded. Wrong study type.

Wassef AW, Zieroth SR, Malik A, and Cordova FJ. (2012) A first in Canada: The St. Boniface Hospital heart failure remote monitoring clinic experience. Canadian Journal of Cardiology 28:S342-S343. Notes: Title/abstract: Excluded. Wrong study type.

Weber H and Schwarz B. (2007) Health economic aspects of ICD and CRT/ICD implantations. Journal fur Kardiologie 14:255-262. Notes: Title/abstract: Excluded. Wrong study type.

Wells GA, Coyle D, Nichol G, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Heart Rhythm 9:S71. Notes: Title/abstract: Excluded. Conference abstract.

Wells GA, Coyle D, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Canadian Journal of Cardiology 28:S419. Notes: Title/abstract: Excluded. Conference abstract.

Yancy CW. (2005) Comprehensive treatment of heart failure: State-of-the-art medical therapy. Reviews in Cardiovascular Medicine 6:S43-S57. Notes: Title/abstract: Excluded. Wrong study type.

Title/abstract: Excluded. Wrong study type.

Yao G, Freemantle N, Calvert MJ, Bryan S, Daubert JC, and Cleland JGF. (2007) The long-term cost-effectiveness of cardiac resynchronization therapy with or without an implantable cardioverter-defibrillator. European Heart Journal 28:42-51. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

Yao G, Freemantle N, Calvert MJ, Bryan S, Daubert JC, and Cleland JG. (2007) The long-term cost-effectiveness of cardiac resynchronization therapy with or without an implantable cardioverter-defibrillator (Structured abstract). European. Heart Journal 28:42-51. Notes: Duplicate

Zhan C, Baine WB, Sedrakyan A, and Steiner C. (2008) Cardiac device implantation in the United States from 1997 through 2004: A population-based analysis. Journal of General Internal Medicine 23:13-19. Notes: Title/abstract: Excluded. Wrong study type.

(2001) Cardial resynchronisation therapy - CRT (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2001) Atrio-biventricular pacing in severe heart failure - horizon scanning review (Structured abstract). Health Technology Assessment. Database.5. Notes: Title/abstract: Excluded. Wrong study type.

(2005) Implantable cardioverter-defibrillators for the primary prevention of sudden cardiac death due to ventricular arrhythmias (Structured abstract). Health Technology Assessment. Database.24. Notes: Title/abstract: Excluded. Wrong study type

(2005) Cardiac resynchronization therapy: multi-site pacemaker use (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2005) The use of cardiac resynchronization therapy (CRT) for heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

(2006) Implantable cardioverter defibrillators for prevention of sudden cardiac death (Structured abstract). Health Technology Assessment. Database.264. Notes: Title/abstract: Included. Full text: Excluded. Wrong indication.

(2009) Abstracts - Belgian Society of Cardiology Belgian Heart Rhythm Association, BeHRA: The 3rd Belgian Heart Rhythm Meeting 'Arrhythmias for Every Cardiologist'. Acta Cardiologica 64. Notes: Title/abstract: Excluded. Wrong study type.

(2009) Cardiac resynchronization therapy for mild congestive heart failure (Structured abstract). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type

(2010) Update on current care guidelines. Current care guideline: cardiac pacemaker therapy. Duodecim; lÃ¤Ã¤ketieteellinen aikakauskirja 126:391-392. Notes: Title/abstract: Excluded. Wrong study type.

(2012) Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120) (Project record). Health Technology Assessment. Database. Notes: Title/abstract: Excluded. Wrong study type.

LITERATURE SEARCH FOR UTILITIES

Literature search date: 30 April 2013

Abdulla J, Kober L, and Torp-Pedersen C. (2004) Methods of assessing the functional status of patients with left ventricular systolic dysfunction in interventional studies: Can brain natriuretic peptide measurement be used as surrogate for the traditional methods. Cardiovascular Drugs and Therapy 18:219-224. Notes: Title/abstract: Excluded. Wrong study type.

Abenstein JP. (2006) Technology Assessment for the Anesthesiologist. Anesthesiology Clinics of North America 24:677-696. Notes: Title/abstract: Excluded. Wrong study type.

Abraham WT, Trupp RJ, Phillilps B, Bourge RC, Bailey B, Harding SM, Schofield P, Pilsworth S, Shneerson JM, Di Salvo T, Camuso J, Johnson D, King M, and Javaheri S. (2006) Validation and clinical utility of a simple in-home testing tool for sleep-disordered breathing and arrhythmias in heart

failure: results of the Sleep Events, Arrhythmias, and Respiratory Analysis in Congestive Heart Failure (SEARCH) study. Congestive heart failure (Greenwich, Conn.) 12:241-247. Notes: Title/abstract: Excluded. Wrong study type.

Adgey AAJ, Spence MS, and Welsh SJ. (2005) Theory and practice of defibrillation: (2) Defibrillation for ventricular fibrillation. Heart 91:118-125. Notes: Title/abstract: Excluded. Wrong study type.

Ahern RM, Lozano R, Naghavi M, Foreman K, Gakidou E, and Murray CJL. (2011) Improving the public health utility of global cardiovascular mortality data: The rise of ischemic heart disease. Population Health Metrics 9. Notes: Title/abstract: Excluded. Wrong study type.

Aidelsburger P, Grabein K, Klauss V, and Wasem J. (2008) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator (CRT-D) for the treatment of chronic heart failure from a German health care systemperspective. Clinical Research in Cardiology 97:89-97. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Lewis 2001 and Yao 2007.

Akerborg O, Nilsson J, Bascle S, Lindgren P, and Reynolds M. (2012) Cost-Effectiveness of Dronedarone in Atrial Fibrillation: Results for Canada, Italy, Sweden, and Switzerland. Clinical Therapeutics 34:1788-1802. Notes: Title/abstract: Excluded. Wrong indication.

Aleem IS, Karamlou T, Benson LN, and McCrindle BW. (2006) Transcatheter device versus surgical closure of ventricular septal defects: A clinical decision analysis. Catheterization and Cardiovascular Interventions 67:630-636. Notes: Title/abstract: Excluded. Wrong indication

Alehagen U, Rahmqvist M, Paulsson T, and Levin LA. (2008) Quality-adjusted life year weights among elderly patients with heart failure. European Journal of Heart Failure 10:1033-1039. Notes: Title/abstract: Included. Full text: Included. TTO.

Almeida J, Felix J, Renkens M, and Alegre P. (2009) Cost-effectiveness of ivabradine in patients with chronic stable angina in a dutch setting. Value in Health 12:A330-A331. Notes: Title/abstract: Excluded. Wrong study type.

Almenar-Pertejo M, Almenar L, Martinez-Dolz L, Campos J, Galan J, Girones P, Ortega F, Ortega T, Rebollo P, and Salvador A. (2006) Study on Health-Related Quality of Life in Patients With Advanced Heart Failure Before and After Transplantation. Transplantation Proceedings 38:2524-2526. Notes: Title/abstract: Excluded. Wrong indication.

Alva ML, Gray A, Mihaylova B, and Clarke P. (2010) Estimating the quality of life impact of diabetes related complications: New results from the UKPDS. Diabetologia 53:S52. Notes: Title/abstract: Excluded. Wrong indication.

Alva ML, Gray A, Mihaylova B, and Clarke P. (2011) The effect of diabetes complications on health-related quality of life: Estimating the bias due to unobserved heterogeneity using the UKPDS. Trials 12. Notes: Title/abstract: Excluded. Wrong indication.

Amaral LM, Fernandes RA, Vasconcellos JF, Takemoto M, Fujii RK, Furlan F, and Mould J. (2012) Health-related quality of life in familial amyloidotic polyneuropathy before and after liver transplantation: A systematic literature review. Value in Health 15:A406-A407. Notes: Title/abstract: Excluded. Wrong indication.

Anaya P, Juarez-Garcia A, Vargas-Valencia J, Uc-Coyoc R, Donato BM, and Islas S. (2010) Economic and health consequences of the use of a DPP4 plus metphormine scheme in the treatment of patients with type 2 diabetes in mexico from the private perspective. Value in Health 13:A60. Notes: Title/abstract: Excluded. Wrong indication.

Anderson AN, Moodley I, and Kropman K. (2000) A South African pharmaco-economic analysis of the acute infarction ramipril efficacy (AIRE) study. Cardiovascular Journal of Southern Africa 11:89-94. Notes: Title/abstract: Excluded. Wrong indication.

Appel LJ and Anderson CAM. (2010) Compelling evidence for public health action to reduce salt intake. New England Journal of Medicine 362:650-652. Notes: Title/abstract: Excluded. Wrong study type.

Arenja N, Potocki M, Ziller R, Mosimann T, Heinisch C, Stelzig C, Freese M, and Mueller C. (2012) Differences in general health status and functional capacity in patient with chronic heart failure and chronic obstructive pulmonary disease after one-year of hospital discharge. European Heart Journal 33:337-338. Notes: Title/abstract: Excluded. Wrong study type

Arreola-Ornelas H, Rosado-Buzzo A, Garcia-Mollinedo L, Dorantes-Aguilar J, Mucino-Ortega E, and Mould-Quevedo JF. (2010) Cost-effectiveness of sildenafil in the management of pulmonary arterial hypertension in mexican adult patients. Value in Health 13:A5. Notes: Title/abstract: Excluded. Wrong indication.

Arya A, Haghjoo M, and Sadr-Ameli MA. (2006) ICD therapy: What have we learned from the clinical trials? Heart Lung and Circulation 15:3-11. Notes: Title/abstract: Excluded. Wrong study type.

Aschauer S, Sterz F, Laggner A, and Behringer W. (2012) Cost-effectiveness of therapeutic hypothermia in post cardiac arrest patients. Resuscitation 83:e20. Notes: Title/abstract: Excluded. Wrong indication.

Athyros VG, Papageorgiou AA, Mercouris BR, Athyrou VV, Symeonidis AN, Basayannis EO, Demitriadis DS, and Kontopoulos AG. (2002) Treatment with atorvastatin to the National Cholesterol Educational Program goal versus 'usual' care in secondary coronary heart disease prevention: The Greek atorvastatin and coronary-heart-disease evaluation (GREACE) study. Current Medical Research and Opinion 18:220-228. Notes: Title/abstract: Excluded. Wrong indication.

Athyros VG, Mikhailidis DP, Liberopoulos EN, Kakafika AI, Karagiannis A, Papageorgiou AA, Tziomalos K, Ganotakis ES, and Elisaf M. (2007) Effect of statin treatment on renal function and serum uric acid levels and their relation to vascular events in patients with coronary heart disease and metabolic syndrome. Nephrology Dialysis Transplantation 22:118-127. Notes: Title/abstract: Excluded. Wrong indication.

Atkins DL. (2010) Realistic expectations for public access defibrillation programs. Current Opinion in Critical Care 16:191-195. Notes: Title/abstract: Excluded. Wrong study type.

Atsumi T, Sakamoto T, Morimura N, Nagao K, Asai Y, Yokota H, Tahara Y, Nara S, Hase M, Sato S, Ariyoshi K, and Asaka Y. (2011) Cost effectiveness analysis of ECPR - Result from SAVE-J the multicenter study. Resuscitation 82:S4. Notes: Title/abstract: Excluded. Wrong indication.

Austin J, Williams R, Ross L, Moseley L, and Hutchison S. (2005) Randomised controlled trial of cardiac rehabilitation in elderly patients with heart failure. European Journal of Heart Failure 7:411-417. Notes: Title/abstract: Included. Full text: Included. EQ-5D.

Austin J, Williams WR, Ross L, and Hutchison S. (2008) Five-year follow-up findings from a randomized controlled trial of cardiac rehabilitation for heart failure. European Journal of Cardiovascular Prevention and Rehabilitation 15:162-167. Notes: Title/abstract: Included. Full text: Included. EQ-5D

Austin J, Williams WR, and Hutchison S. (2009) Multidisciplinary management of elderly patients with chronic heart failure: Five year outcome measures in death and survivor groups. European Journal of Cardiovascular Nursing 8:34-39. Notes: Title/abstract: Excluded. Wrong study type.

Axelrod DA. (2013) Economic and financial outcomes in transplantation: Whose dime is it anyway? Current Opinion in Organ Transplantation 18:222-228. Notes: Title/abstract: Excluded. Wrong study type.

Azagury DE and Lautz DB. (2011) Obesity Overview: Epidemiology, Health and Financial Impact, and Guidelines for Qualification for Surgical Therapy. Gastrointestinal Endoscopy Clinics of North America 21:189-201. Notes: Title/abstract: Excluded. Wrong study type.

Baliga RR and Young JB. (2009) Editorial. Do Biomarkers Deserve High Marks? Heart Failure Clinics 5:ix-xii. Notes: Title/abstract: Excluded. Wrong study type.

Banka G, Heidenreich PA, and Fonarow GC. (2013) Incremental cost-effectiveness of guideline-directed medical therapies for heart failure. Journal of the American College of Cardiology 61:1440-1446. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Dyer 2010

Bannon M. (2009) Elements: In this month's issue. QJM 102:303-304. Notes: Title/abstract: Excluded. Wrong study type.

Banz K. (2005) Cardiac resynchronization therapy (CRT) in heart failure - A model to assess the economic value of this new medical technology. Value in Health 8:128-139. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Lewis 2001.

Barry M and Tilson L. (2007) Recent developments in pricing and reimbursement of medicines in Ireland. Expert Review of Pharmacoeconomics and Outcomes Research 7:605-611. Notes: Title/abstract: Excluded. Wrong study type.

Bassi A and Bodger K. (2003) QALYs in IBD - What, when and how? CME Journal Gastroenterology, Hepatology and Nutrition 5:59-64. Notes: Title/abstract: Excluded. Wrong study type.

Beaudet A, Clegg JP, and Lloyd A. (2012) Systematic literature review of utility values associated with type 2 diabetes-related complications. Value in Health 15:A503. Notes: Title/abstract: Excluded. Wrong indication.

Bellia V, Battaglia S, Matera MG, and Cazzola M. (2006) The use of bronchodilators in the treatment of airway obstruction in elderly patients. Pulmonary Pharmacology and Therapeutics 19:311-319. Notes: Title/abstract: Excluded. Wrong study type.

Bennett J and Glasziou P. (2003) Ins and outs of the pharmaceutical benefits scheme. Medicine Today 4:105-110. Notes: Title/abstract: Excluded. Wrong study type.

Bensimhon DR, Adams GL, Whellan DJ, Pagnanelli RA, Trimble M, Lee BA, Lee KL, Ellis SJ, Kraus WE, Rendall DS, Iskandrian AE, O'Connor CM, and Borges-Neto S. (2007) Effect of exercise training on ventricular function, dyssynchrony, resting myocardial perfusion, and clinical outcomes in patients with heart failure: A nuclear ancillary study of Heart Failure and A Controlled Trial Investigating Outcomes of Exercise TraiNing (HF-ACTION); design and rationale. American Heart Journal 154:46-53. Notes: Title/abstract: Excluded. Wrong study type.

Benvenuto GM, Ometto R, Fontanelli A, Fortunato A, Ruffini PA, Fosser V, and Morandi P. (2003) Chemotherapy-related cardiotoxicity: new diagnostic and preventive strategies. Italian heart journal : official journal of the Italian Federation of Cardiology 4:655-667. Notes: Duplicate

Benvenuto GM, Ometto R, Fontanelli A, Fortunato A, Ruffini PA, Fosser V, and Morandi P. (2003) Chemotherapy-related cardiotoxicity: New diagnostic and preventive strategies. Italian Heart Journal 4:655-667. Notes: Title/abstract: Excluded. Wrong study type.

Bereza BG, Machado M, and Einarson TR. (2009) Systematic review and quality assessment of economic evaluations and quality-of-life studies related to generalized anxiety disorder. Clinical Therapeutics 31:1279-1308. Notes: Title/abstract: Excluded. Wrong indication.

Berg J, Lindgren P, Nieuwlaat R, Bouin O, and Crijns H. (2010) Factors determining utility measured with the EQ-5D in patients with atrial fibrillation. Quality of Life Research1-10. Notes: Title/abstract: Excluded. Wrong indication.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Bertoldi EG, Rohde LE, Zimerman LI, Pimentel M, and Polanczyk CA. (2013) Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle-income country's public health system. International Journal of Cardiology 163:309-315. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Gohler 2009.

Biccard BM. (2008) A peri-operative statin update for non-cardiac surgery. Part II: Statin therapy for vascular surgery and peri-operative statin trial design. Anaesthesia 63:162-171. Notes: Title/abstract: Excluded. Wrong study type.

Biem HJ, Detsky AS, and Armstrong PW. (1990) Management of asymptomatic chronic aortic regurgitation with left ventricular dysfunction: A decision analysis. Journal of General Internal Medicine 5:394-401. Notes: Title/abstract: Excluded. Wrong study type

Bieniarz MC and Delgado R. (2007) The financial burden of destination left ventricular assist device therapy: Who and when? Current Cardiology Reports 9:194-199. Notes: Title/abstract: Excluded. Wrong study type.

Bierwirth R, Liebl A, and Gschwend MH. (2010) Cost-effectiveness of pioglitazone in patients with type2 diabetes and a history of macrovascular disease in Germany. Diabetologie und Stoffwechsel 5:32-39. Notes: Title/abstract: Excluded. Wrong indication.

Birks EJ. (2010) The comparative use of ventricular assist devices: Differences between Europe and the United States. Texas Heart Institute Journal 37:565-567. Notes: Title/abstract: Excluded. Wrong study type

Birks EJ, Slaughter MS, Boyce SW, McGee EC, Cotts WG, Najjar SS, Pagani FD, Hathaway D, Jacoski MV, Najarian KB, and Aaronson KD. (2012) Improved quality of life and functional capacity for patients receiving the hvad(registered trademark) pump. Circulation 126. Notes: Title/abstract: Excluded. Wrong indication

Birnie DH and Tang ASL. (2006) The problem of non-response to cardiac resynchronization therapy. Current Opinion in Cardiology 21:20-26. Notes: Title/abstract: Excluded. Wrong study type.

Blank PR, Schwenkglenks M, and Szucs TD. (2010) Cost-effectiveness of ferric carboxymaltose in patients with chronic heart failure: An analysis from the FAIR-HF trial. European Heart Journal 31:225. Notes: Title/abstract: Excluded. Wrong study type.

Blom DJ. (2012) Statin therapy for the octogenarian? Journal of Endocrinology, Metabolism and Diabetes of South Africa 17:37-42. Notes: Title/abstract: Excluded. Wrong study type.

Blomstrom P, Ekman M, Blomstrom Lundqvist C, Calvert MJ, Freemantle N, Lonnerholm S, Wikstrom G, and Jonsson B. (2008) Cost effectiveness of cardiac resynchronization therapy in the Nordic region: An analysis based on the CARE-HF trial. European Journal of Heart Failure 10:869-877. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication based on CARE-HF. Utilities not reported in detail.

Bockerman P, Johansson E, and Saarni SI. (2011) Do established health-related quality-of-life measures adequately capture the impact of chronic conditions on subjective well-being? Health Policy 100:91-95. Notes: Title/abstract: Excluded. Wrong study type.

Boland A, Dundar Y, Bagust A, Haycox A, Hill R, Mujica Mota R, Walley T, and Dickson R. (2003) Early thrombosis for the treatment of acute myocardial infarction: A systematic review and economic evaluation. Health Technology Assessment 7. Notes: Title/abstract: Excluded. Wrong indication

Bond M, Mealing S, Anderson R, Dean J, Stein K, and Taylor RS. (2009) Is combined resynchronisation and implantable defibrillator therapy a cost-effective option for left ventricular dysfunction? International Journal of Cardiology 137:206-215. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Calvert 2005.

Borgeson DD, Defranchi SA, Lam CSP, Lin G, and Nichols FC. (2009) Chronic indwelling pleural catheters reduce hospitalizations in advanced heart failure with refractory pleural effusions. Journal of Cardiac Failure 15:S105. Notes: Title/abstract: Excluded. Wrong study type

Borghi,C. Efficacy and tolerability of valsartan in cardiovascular disease. Hot Topics in Hypertension [5], 7-15. 2009. Ref Type: Generic Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Biffi M, Martignani C, Camanini C, Grigioni F, Rapezzi C, and Branzi A. (2003) Cardioverter-defibrillators after MADIT-II: The balance between weight of evidence and treatment costs. European Journal of Heart Failure 5:419-425. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Biffi M, Martignani C, Valzania C, Diemberger I, Bertini M, Domenichini G, Ziacchi M, and Branzi A. (2009) Is cardiac resynchronization therapy cost-effective? Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology 11 Suppl 5:v93-v97. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Mantovani LG, Biffi M, Schalij MJ, Martignani C, Leclercq C, Bax JJ, and Auricchio A. (2011) Cardiac resynchronization therapy: A cost or an investment? Europace 13:ii32-ii38. Notes: Title/abstract: Excluded. Wrong study type.

Boriani G, Diemberger I, Biffi M, and Martignani C. (2012) Cost-effectiveness of cardiac resynchronisation therapy. Heart 98:1828-1836. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Borras Perez X. (2007) Economic criteria for selecting new therapies for use by clinical cardiologists. Revista Espanola de Cardiologia Suplementos 7:12C-20C. Notes: Title/abstract: Excluded. Wrong study type.

Bouma BJ and Van Der Sloot JA. (2011) Utility of contrast echocardiography to detect Baffle leak in mustard patients. Echocardiography 28:E154-E155. Notes: Title/abstract: Excluded. Wrong study type.

Boyko J, Glick HA, and Schulman KA. (1999) Economics and cost-effectiveness in evaluating the value of cardiovascular therapies. ACE inhibitors in the management of congestive heart failure: comparative economic data. American Heart Journal 137:S115-S119. Notes: Title/abstract: Excluded. Wrong study type

Boyne JJJ, Vrijhoef HJM, Wit RD, and Gorgels APM. (2011) Telemonitoring in patients with heart failure, the TEHAF study: Study protocol of an ongoing prospective randomised trial. International Journal of Nursing Studies 48:94-99. Notes: Title/abstract: Excluded. Wrong study type

Bradshaw PJ, Jamrozik KD, Gilfillan IS, and Thompson PL. (2006) Asymptomatic long-term survivors of coronary artery bypass surgery enjoy a quality of life equal to the general population. American Heart Journal 151:537-544. Notes: Title/abstract: Excluded. Wrong indication

Bramlage P and Schindler C. (2010) Differences in pharmacology and their translation into differences in clinical efficacy - A comparison of the renin angiotensin blocking agents irbesartan and losartan. Expert Opinion on Pharmacotherapy 11:521-535. Notes: Title/abstract: Excluded. Wrong study type.

Brandle M, Erny-Albrecht KM, Goodall G, Spinas GA, Streit P, and Valentine WJ. (2009) Exenatide versus insulin glargine: A cost-effectiveness evaluation in patients with Type 2 diabetes in Switzerland. International Journal of Clinical Pharmacology and Therapeutics 47:501-515. Notes: Title/abstract: Excluded. Wrong indication.

Brandle M, Azoulay M, and Greiner RA. (2011) Cost-effectiveness of insulin glargine versus NPH insulin for the treatment of Type 2 diabetes mellitus, modeling the interaction between hypoglycemia and glycemic control in Switzerland. International Journal of Clinical Pharmacology and Therapeutics 49:217-230. Notes: Title/abstract: Excluded. Wrong indication.

Braun J, McHugh N, Singh A, Wajdula JS, and Sato R. (2007) Improvement in patient-reported outcomes for patients with ankylosing spondylitis treated with etanercept 50 mg once-weekly and 25 mg twice-weekly. Rheumatology 46:999-1004. Notes: Title/abstract: Excluded. Wrong indication.

Brennan A, Thokala P, Baalbaki H, Stevens JW, Wang J, and Pandor A. (2012) Telemonitoring after discharge with heart failure-costeffectiveness modelling of alternative service designs. Value in Health 15:A360. Notes: Title/abstract: Excluded. Wrong study type.

Brereton N, Winn B, and Akehurst R. (2012) The cost-effectiveness of celecoxib vs diclofenac in the treatment of osteoarthritis in the UK; an update to the NICE model using data from the CONDOR trial. Journal of Medical Economics 15:465-472. Notes: Title/abstract: Excluded. Wrong indication.

Brereton NJ, Craig AM, and Akehurst R. (2010) Cost-effectiveness of dronedarone for the treatment of atrial fibrillation in the UK. Value in Health 13:A357. Notes: Title/abstract: Excluded. Wrong study type.

Briggs A, Mihaylova B, Sculpher M, Hall A, Wolstenholme J, Simoons M, Deckers J, Ferrari R, Remme WJ, Bertrand M, and Fox K. (2007) Cost effectiveness of perindopril in reducing cardiovascular events in patients with stable coronary artery disease using data from the EUROPA study. Heart 93:1081-1086. Notes: Title/abstract: Excluded. Wrong indication

Brown CS and Bertolet BD. (1998) Peripartum cardiomyopathy: A comprehensive review. American Journal of Obstetrics and Gynecology 178:409-414. Notes: Title/abstract: Excluded. Wrong study type.

Brown KL. (2008) Economic evaluation in paediatric practice: Examples from cardiac critical care. Current Pediatric Reviews 4:270-274. Notes: Title/abstract: Excluded. Wrong indication

Brown KL, Wray J, Wood TL, Mc Mahon AM, Burch M, and Cairns J. (2009) Cost Utility Evaluation of Extracorporeal Membrane Oxygenation as a Bridge to Transplant for Children With End-Stage Heart Failure due to Dilated Cardiomyopathy. Journal of Heart and Lung Transplantation 28:32-38. Notes: Title/abstract: Excluded. Wrong indication

Brunner-La Rocca HP, Rickenbacher P, Muzzarelli S, Schindler R, Maeder MT, Jeker U, Kiowski W, Leventhal ME, Pfister O, Osswald S, Pfisterer ME, and Rickli H. (2012) End-of-life preferences of elderly patients with chronic heart failure. European Heart Journal 33:752-759. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Bryan J. (2012) How spironolactone became the next best thing for severe heart failure. Pharmaceutical Journal 288:88-89. Notes: Title/abstract: Excluded. Wrong study type.

Bryant J, Brodin H, Loveman E, Payne E, and Clegg A. (2005) The clinical and cost-effectiveness of implantable cardioverter defibrillators: A systematic review. Health Technology Assessment 9:iii-43. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. Does not report utilities in detail.

Buendia Rodriguez JA and Vallejos C. (2011) A cost-effectiveness analysis of adjuvant trastuzumab regimens in early HER2/NEU-positive breast cancer in colombia. Value in Health 14:A449. Notes: Title/abstract: Excluded. Wrong study type.

Bulkova V, Fiala M, Wichterle D, Chovancik J, Simek J, Havranek S, Brada J, Tolaszova H, Branny M, and Ivanova K. (2009) Demographic and medical characteristics of patients undergoing catheter ablation for different forms of atrial fibrillation. Journal of Cardiovascular Electrophysiology 20:S29. Notes: Title/abstract: Excluded. Wrong study type.

Butler CR and Jugdutt BI. (2012) Mechanical circulatory support for elderly heart failure patients. Heart Failure Reviews 17:663-669. Notes: Title/abstract: Excluded. Wrong study type.

Butterfield JA, Faddy SC, Davidson P, and Ridge B. (2008) Exercise training in patients with stable chronic heart failure: Effects on thoracic impedance cardiography and B-type natriuretic peptide. Journal of Cardiopulmonary Rehabilitation and Prevention 28:33-37. Notes: Title/abstract: Excluded. Wrong study type.

Calabrese D. (2011) Improving outcomes in chronic kidney disease: Optimizing management of cardiovascular diseases. American Journal of Pharmacy Benefits 3:345-351. Notes: Title/abstract: Excluded. Wrong study type.

Callejo D, Guerra M, Hernandez-Madrid A, and Blasco JA. (2010) Economic assessment of cardiac resynchronization therapy. Revista Espanola de Cardiologia 63:1235-1243. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References De Rivas 2008.

Calvert MJ, Freemantle N, Yao G, Cleland JGF, Billingham L, Daubert JC, and Bryan S. (2005) FASTTRACK Cost-effectiveness of cardiac resynchronization therapy: Results from the CARE-HF trial. European Heart Journal 26:2681-2688. Notes: Duplicate

Calvert MJ, Freemantle N, Yao G, Cleland JG, Billingham L, Daubert JC, and Bryan S. (2005) Cost-effectiveness of cardiac resynchronization therapy: results from the CARE-HF trial. European Heart Journal 26:2681-2688. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. Does not report utilities in detail.

Cameron CG and Bennett Bpharm HA. (2009) Cost-effectiveness of insulin analogues for diabetes mellitus. CMAJ 180:400-407. Notes: Title/abstract: Excluded. Wrong indication.

Cannizzaro LA, Piccini JP, Patel UD, and Hernandez AF. (2011) Device therapy in heart failure patients with chronic kidney disease. Journal of the American College of Cardiology 58:889-896. Notes: Title/abstract: Excluded. Wrong study type.

Capomolla S, Febo O, Ceresa M, Caporotondi A, Guazzotti G, La Rovere MT, Ferrari M, Lenta F, Baldin S, Vaccarini C, Gnemmi M, Pinna G, Maestri R, Abelli P, Verdirosi S, and Cobelli F. (2002) Cost/utility ratio in chronic heart failure: Comparison between heart failure management program delivered by day-hospital and usual care. Journal of the American College of Cardiology 40:1259-1266. Notes: Title/abstract: Included. Full text: Included. TTO

Cappato R, Curnis A, Marzollo P, Mascioli G, Bordonali T, Beretti S, Scalfi F, Bontempi L, Carolei A, Bardy G, De Ambroggi L, and Cas LD. (2006) Prospective assessment of integrating the existing emergency medical system with automated external defibrillators fully operated by volunteers and laypersons for out-of-hospital cardiac arrest: The Brescia Early Defibrillation Study (BEDS). European Heart Journal 27:553-561. Notes: Title/abstract: Excluded. Wrong indication

Carels RA. (2004) The association between disease severity, functional status, depression and daily quality of life in congestive heart failure patients. Quality of Life Research 13:63-72. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Carides GW. (2007) Losartan: A pharmacoeconomic review. Journal of Medical Economics 10:573-585. Notes: Title/abstract: Excluded. Wrong study type.

Carney PA. (2004) Biennial screening mammography is cost effective in healthy women aged over 65 years. Evidence-Based Healthcare 8:142-144. Notes: Title/abstract: Excluded. Wrong study type.

Caro JJ, Guo S, Ward A, Chalil S, Malik F, and Leyva F. (2006) Modelling the economic and health consequences of cardiac resynchronization therapy in the UK. Current Medical Research and Opinion 22:1171-1179. Notes: Title/abstract: Included. Full text: Excluded. References Calvert 2005.

Caronna JJ and Ougorets I. (2002) Cost effectiveness of aggressive care in nontraumatic coma. Critical Care Medicine 30:1382-1383. Notes: Title/abstract: Excluded. Wrong indication

Carter NJ and Keating GM. (2010) Glatiramer acetate: A review of its use in relapsing-remitting multiple sclerosis and in delaying the onset of clinically definite multiple sclerosis. Drugs 70:1545-1577. Notes: Title/abstract: Excluded. Wrong study type.

Caviness AC, Cantor SB, Allen CH, and Ward MA. (2004) A Cost-Effectiveness Analysis of Bacterial Endocarditis Prophylaxis for Febrile Children Who Have Cardiac Lesions and Undergo Urinary Catheterization in the Emergency Department. Pediatrics 113:1291-1296. Notes: Title/abstract: Excluded. Wrong indication.

Cesar LAM, Gowdak LH, and Mansur AP. (2009) The metabolic treatment of patients with coronary artery disease: Effects on quality of life and effort Angina. Current Pharmaceutical Design 15:841-849. Notes: Title/abstract: Excluded. Wrong indication.

Chaiamnuay S, Allison JJ, and Curtis JR. (2006) Risks versus benefits of cyclooxygenase-2-selective nonsteroidal antiinflammatory drugs. American Journal of Health-System Pharmacy 63:1837-1851. Notes: Title/abstract: Excluded. Wrong study type

Chambers MG, Narula J, and Cerqueira MD. (2002) The economic burden of heart failure and implantable cardioverter defibrillators: The value of noninvasive imaging of high-risk patients. Journal of Nuclear Cardiology 9:S71-S80. Notes: Title/abstract: Excluded. Wrong study type.

Chan PS, Soto G, Jones PG, Nallamothu BK, Zhang Z, Weintraub WS, and Spertus JA. (2009) Patient health status and costs in heart failure. Insights from the eplerenone post-acute myocardial infarction heart failure efficacy and survival study (EPHESUS). Circulation 119:398-407. Notes: Title/abstract: Excluded. Wrong study type.

Chao CT. (2011) Behind intravenous iron therapy for heart failure: The downside? International Journal of Clinical Practice 65:1014. Notes: Title/abstract: Excluded. Wrong study type.

Charles MES, Sadri H, Minshall ME, and Tunis SL. (2009) Health economic comparison between continuous subcutaneous insulin infusion and multiple daily injections of insulin for the treatment of adult type 1 diabetes in Canada. Clinical Therapeutics 31:657-667. Notes: Title/abstract: Excluded. Wrong indication.

Chee A and Tremblay A. (2011) The use of tunneled pleural catheters in the treatment of pleural effusions. Current Opinion in Pulmonary Medicine 17:237-241. Notes: Title/abstract: Excluded. Wrong study type.

Chen L and Hay JW. (2004) Cost-effectiveness of primary implanted cardioverter defibrillator for sudden death prevention in congestive heart failure. Cardiovascular Drugs and Therapy 18:161-170. Notes: Title/abstract: Included. Full text: Included. LIterature based estimates

Chen R, Lee E, Lim TW, Seow SC, Chai P, Wong R, and Lam C. (2012) Preference for symptom versus survival improvement among Asian patients with heart failure. Journal of the American College of Cardiology 59:E1917. Notes: Title/abstract: Excluded. Wrong indication.

Chen YS, Lin JW, and Lin FY. (2008) CPR with assisted extracorporeal life support - Authors' reply. The Lancet 372:1879-1880. Notes: Title/abstract: Excluded. Wrong study type.

Chih S, Macdonald PS, McCrohon JA, Ma D, Moore J, Feneley MP, Law M, Kovacic JC, and Graham RM. (2012) Granulocyte colony stimulating factor in chronic angina to stimulate neovascularisation: A placebo controlled crossover trial. Heart 98:282-290. Notes: Title/abstract: Excluded. Wrong study type.

Cintra M, Bahia L, Franco L, Nita ME, and Rached R. (2010) Health related quality of life of type 2 diabetes mellitus patients in the brazilian private health care system: First results of DIAPS79 study. Value in Health 13:A298. Notes: Title/abstract: Excluded. Wrong indication.

Clarke P, Gray A, and Holman R. (2002) Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62). Medical Decision Making 22:340-349. Notes: Title/abstract: Excluded. Wrong indication.

Clarke PM, Hayes AJ, Glasziou PG, Scott R, Simes J, and Keech AC. (2009) Using the EQ-5D index score as a predictor of outcomes in patients with type 2 diabetes. Medical Care 47:61-68. Notes: Title/abstract: Excluded. Wrong indication

Clegg AJ, Scott DA, Loveman E, Colquitt JL, Royle P, and Bryant J. (2006) Clinical and cost-effectiveness of left ventricular assist devices as a bridge to heart transplantation for people with end-stage heart failure: A systematic review and economic evaluation. European Heart Journal 27:2929-2938. Notes: Title/abstract: Excluded. Wrong indication

Clegg AJ, Scott DA, Loveman E, Colquitt J, Royle P, and Bryant J. (2007) Clinical and cost-effectiveness of left ventricular assist devices as destination therapy for people with end-stage heart failure: A systematic review and economic evaluation. International Journal of Technology Assessment in Health Care 23:261-268. Notes: Title/abstract: Excluded. Wrong indication

Cleland J, Chiswell K, Filippatos G, Givertz M, Massie B, Cotter G, Davison B, Fiuzat M, Voors AA, Mansoor G, Ponikowski P, Teerlink J, and O'Connor C. (2012) Quality of life 60 days after an acute heart failure event: Insights from the protect trial. Journal of the American College of Cardiology 59:E1032. Notes: Title/abstract: Excluded. Wrong indication.

Cleland JGF and Walker A. (1997) Is medical treatment for angina the most cost-effective option? European Heart Journal 18:B35-B42. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF. (2002) How to assess new treatments for the management of heart failure: Composite scoring systems to assess the patients' clinical journey. European Journal of Heart Failure 4:243-247. Notes: Title/abstract: Excluded. Wrong study type

Cleland JGF, Charlesworth A, Lubsen J, Swedberg K, Remme WJ, Erhardt L, Di Lenarda A, Komajda M, Metra M, Torp-Pedersen C, and Poole-Wilson PA. (2006) A Comparison of the Effects of Carvedilol and Metoprolol on Well-Being, Morbidity, and Mortality (the "Patient Journey") in Patients With Heart Failure. A Report From the Carvedilol Or Metoprolol European Trial (COMET). Journal of the American College of Cardiology 47:1603-1611. Notes: Title/abstract: Excluded. Wrong study type.

Cleland JGF, Calvert MJ, Verboven Y, and Freemantle N. (2009) Effects of cardiac resynchronization therapy on long-term quality of life: An analysis from the CArdiac Resynchronisation-Heart Failure (CARE-HF) study. American Heart Journal 157:457-466. Notes: Title/abstract: Included. Full text: Included. EQ-5D

Clerico A, Galli C, Fortunato A, and Ronco C. (2012) Neutrophil gelatinase-associated lipocalin (NGAL) as biomarker of acute kidney injury: A review of the laboratory characteristics and clinical evidences. Clinical Chemistry and Laboratory Medicine 50:1505-1517. Notes: Title/abstract: Excluded. Wrong study type.

Coats AJS. (2011) Clinical utility of exercise training in chronic systolic heart failure. Nature Reviews Cardiology 8:380-392. Notes: Title/abstract: Excluded. Wrong study type

Coffey JT, Brandle M, Zhou H, Marriott D, Burke R, Tabaei BP, Engelgau MM, Kaplan RM, and Herman WH. (2002) Valuing health-related quality of life in diabetes. Diabetes Care 25:2238-2243. Notes: Title/abstract: Excluded. Wrong indication

Colantonio LD, Marti SG, and Rubinstein AL. (2010) Economic evaluations on cardiovascular preventive interventions in Argentina. Expert Review of Pharmacoeconomics and Outcomes Research 10:465-473. Notes: Title/abstract: Excluded. Wrong study type

Coleman CI, Straznitskas AD, Sobieraj DM, Kluger J, and Anglade MW. (2012) Cost-effectiveness of clopidogrel plus aspirin for stroke prevention in patients with atrial fibrillation in whom warfarin is unsuitable. American Journal of Cardiology 109:1020-1025. Notes: Title/abstract: Excluded. Wrong indication.

Collins SP, Schauer DP, Gupta A, Brunner H, Storrow AB, and Eckman MH. (2009) Cost-effectiveness analysis of ED decision making in patients with non-high-risk heart failure. American Journal of Emergency Medicine 27:293-302. Notes: Title/abstract: Excluded. Wrong study type

Colombo GL, Caruggi M, Ottolini C, and Maggioni AP. (2008) Candesartan in heart failure: Assessment of reduction in mortality and morbidity (CHARM) and resource utilization and costs in Italy. Vascular Health and Risk Management 4:223-234. Notes: Title/abstract: Excluded. Wrong study type.

Connelly DT. (2009) Current controversies in using electrical devices. European Journal of Heart Failure, Supplement 8:i21-i24. Notes: Title/abstract: Excluded. Wrong study type.

Costello JM, Cooper DS, Jacobs JP, Chai PJ, Kirsch R, Rosenthal T, Dalton HJ, Graziano JN, and Quintessenza JA. (2011) Intermediate-term outcomes after paediatric cardiac extracorporeal membrane oxygenation - What is known (and unknown). Cardiology in the Young 21:118-123. Notes: Title/abstract: Excluded. Wrong study type

Couturier B, Carrat F, Cohen A, and Hejblum G. (2012) Cost-utility of post-discharge educational interventions in patients with acute coronary syndrome or chronic heart failure. Value in Health 15:A122-A123. Notes: Title/abstract: Excluded. Wrong study type.

Covelli H, Bhattacharya S, Cassino C, Conoscenti C, and Kesten S. (2005) Absence of electrocardiographic findings and improved function with once-daily tiotropium in patients with chronic obstructive pulmonary disease. Pharmacotherapy 25:1708-1718. Notes: Title/abstract: Excluded. Wrong indication

Cowie MR. (2009) Evidence-based medicine within a budget - Where should we spend our money? European Journal of Heart Failure, Supplement 8:i36-i38. Notes: Title/abstract: Excluded. Wrong study type

Cowie MR, Cure S, Bianic F, McGuire A, Goodall G, and Tavazzi L. (2011) Cost-effectiveness of highly purified omega-3 polyunsaturated fatty acid ethyl esters in the treatment of chronic heart failure: Results of Markov modelling in a UK setting. European Journal of Heart Failure 13:681-689. Notes: Title/abstract: Included. Full text: Included. Literature based estimates

Craig J, Saxby RC, Homer T, and Swartz MT. (2011) An economic evaluation of the heartware ventricular assist device in the NHS. Value in Health 14:A252. Notes: Title/abstract: Excluded. Wrong study type.

Cram P, Vijan S, Wolbrink A, and Fendrick AM. (2003) The impact of including passive benefits in cost-effectiveness analysis: The case of automated external defibrillators on commercial aircraft. Value in Health 6:466-473. Notes: Title/abstract: Excluded. Wrong study type.

Cram P, Vijan S, and Fendrick AM. (2003) Cost-effectiveness of automated external defibrillator deployment in selected public locations. Journal of General Internal Medicine 18:745-754. Notes: Title/abstract: Excluded. Wrong indication

Cram P, Fendrick AM, and Vijan S. (2003) Public use of automated external defibrillators. The New England journal of medicine 348:755-756. Notes: Title/abstract: Excluded. Wrong study type.

Cram P, Fendrick AM, Vijan S, Groeneveld PW, Caffrey-Villari S, Pepe PE, Isenring P, and Guay G. (2003) Public use of automated external defibrillators [1] (multiple letters). New England Journal of Medicine 348:755-756. Notes: Duplicate

Cram P, Vijan S, Katz D, and Fendrick AM. (2005) Cost-effectiveness of in-home automated external defibrillators for individuals at increased risk of sudden cardiac death: There's no place like home? Journal of General Internal Medicine 20:251-258. Notes: Title/abstract: Excluded. Wrong indication

Cram P, Katz D, Vijan S, Kent DM, Langa KM, and Fendrick AM. (2006) Implantable or external defibrillators for individuals at increased risk of cardiac arrest: Where cost-effectiveness hits fiscal reality. Value in Health 9:292-302. Notes: Title/abstract: Excluded. Wrong indication

Croom KF and Plosker GL. (2005) Eplerenone: A pharmacoeconomic review of its use in patients with post-myocardial infarction heart failure. PharmacoEconomics 23:1057-1072. Notes: Title/abstract: Excluded. Wrong study type

Curtiss FR. (2006) Measuring value in the treatment of symptoms of allergic rhinitis with nasal steroids. Journal of Managed Care Pharmacy 12:168-172. Notes: Title/abstract: Excluded. Wrong study type.

Dankner R, Burya-Sa'adon L, Geulayov G, Kobalyov A, and Drory Y. (2011) [Health-related quality of life of Israeli heart patients according to the MacNew heart disease specific instrument]. Harefuah 150:760-764, 816. Notes: Title/abstract: Excluded. Wrong study type.

Daubert JC, Leclercq C, Donal E, and Mabo P. (2006) Cardiac resynchronisation therapy in heart failure: Current status. Heart Failure Reviews 11:147-154. Notes: Title/abstract: Excluded. Wrong study type.

Davenport C, Cheng EYL, Kwok YTT, Lai AHO, Wakabayashi T, Hyde C, and Connock M. (2006) Assessing the diagnostic test accuracy of natriuretic peptides and ECG in the diagnosis of left ventricular systolic dysfunction: A systematic review and meta-analysis. British Journal of General Practice 56:48-56. Notes: Title/abstract: Excluded. Wrong study type.

Davidson P, Cockburn J, Daly J, and Sanson Fisher R. (2004) Patient-centered needs assessment: rationale for a psychometric measure for assessing needs in heart failure. The Journal of cardiovascular nursing 19:164-171. Notes: Title/abstract: Excluded. Wrong study type.

De Ferrari GM and Sanzo A. (2009) T-wave alternans in risk stratification of patients with nonischemic dilated cardiomyopathy: Can it help to better select candidates for ICD implantation? Heart Rhythm 6:S29-S35. Notes: Title/abstract: Excluded. Wrong study type

De Rivas B, Permanyer-Miralda G, Brotons C, Aznar J, and Sobreviela E. (2008) Health-related quality of life in unselected outpatients with heart failure across Spain in two different health care levels. Magnitude and determinants of impairment: The INCA study. Quality of Life Research 17:1229-1238. Notes: Title/abstract: Included. Full text: Included. EQ-5D

de Vries AE, de Jong RM, van der Wal MH, Jaarsma T, van Dijk RB, and Hillege HL. (2011) The value of INnovative ICT guided disease management combined with Telemonitoring in OUtpatient clinics for Chronic Heart failure patients. Design and methodology of the IN TOUCH study: a multicenter randomised trial. BMC health services research 11:167. Notes: Title/abstract: Excluded. Wrong study type.

de CM. (2005) Limitations and perspectives with the approach to rheumatic fever and rheumatic heart disease. Cardiology in the Young 15:580-582. Notes: Title/abstract: Excluded. Wrong study type.

Deedwania PC and Smith DG. (2007) Clinical efficacy and cost-effectiveness of rosuvastatin. Expert Review of Pharmacoeconomics and Outcomes Research 7:31-39. Notes: Title/abstract: Excluded. Wrong study type.

Degrauwe N, Sosa JA, Roman S, and Deshpande HA. (2012) Vandetanib for the treatment of metastatic Medullary thyroid cancer. Clinical Medicine Insights: Oncology 6:243-252. Notes: Title/abstract: Excluded. Wrong study type.

Del Canizo J, Rodriguez-Martinez D, Perez-Caballero R, Quintana B, and Ruiz-Fernandez M. (2010) Low-cost pulsatile cardiac assist device with compliant input chamber. Artificial Organs 34:136-140. Notes: Title/abstract: Excluded. Wrong study type

Delea TE, Karnon J, Sofrygin O, Thomas SK, Papo NL, and Barghout V. (2007) Cost-effectiveness of letrozole versus tamoxifen as initial adjuvant therapy in hormone receptor-positive postmenopausal women with early-stage breast cancer. Clinical Breast Cancer 7:608-618. Notes: Title/abstract: Excluded. Wrong indication.

Delea TE, El-Ouagari K, Karnon J, and Sofrygin O. (2008) Cost-effectiveness of letrozole versus tamoxifen as initial adjuvant therapy in postmenopausal women with hormone-receptor positive early breast cancer from a Canadian perspective. Breast Cancer Research and Treatment 108:375-387. Notes: Title/abstract: Excluded. Wrong indication.

Delgado DH, Ross HJ, and Rao V. (2007) The dilemma of a left ventricular assist device explantation: A decision analysis. Canadian Journal of Cardiology 23:657-661. Notes: Title/abstract: Excluded. Wrong study type.

Desai SP, Solomon DH, Abramson SB, Buckley L, Crofford LJ, Cosh JJ, Lovell DJ, and Saag KG. (2008) Recommendations for use of selective and nonselective nonsteroidal antiinflammatory drugs: An American College of Rheumatology white paper. Arthritis Care and Research 59:1058-1073. Notes: Title/abstract: Excluded. Wrong study type.

Deshpande H, Marler V, and Sosa JA. (2011) Clinical utility of vandetanib in the treatment of patients with advanced medullary thyroid cancer. OncoTargets and Therapy 4:209-215. Notes: Title/abstract: Excluded. Wrong indication.

Deshpande HA, Sheth K, Sosa JA, and Roman S. (2012) Efficacy and tolerability of pharmacotherapy options for the treatment of medullary thyroid cancer. Clinical Medicine Insights: Oncology 6:355-362. Notes: Title/abstract: Excluded. Wrong study type

Dev S, Clare R, Fiuzat M, Michael Felker G, and O'Connor CM. (2010) The association of do-not-resuscitate preference with quality of life preference and mortality in patients in the ESCAPE trial. Journal of Cardiac Failure 16:S103. Notes: Title/abstract: Excluded. Wrong study type.

Dev S, Clare RM, Felker GM, Fiuzat M, Stevenson LW, and O'Connor CM. (2012) Link between decisions regarding resuscitation and preferences for quality over length of life with heart failure. European Journal of Heart Failure 14:45-53. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Dhillon S, Lyseng-Williamson KA, and Scott LJ. (2007) Etanercept: A review of its use in the management of rheumatoid arthritis. Drugs 67:1211-1241. Notes: Title/abstract: Excluded. Wrong study type

Diaz-Dominguez R, Perez-Bernal J, Perez-San-Gregorio MA, and Martin-Rodriguez A. (2006) Quality of Life in Patients With Kidney, Liver or Heart Failure During the Waiting List Period. Transplantation Proceedings 38:2459-2461. Notes: Title/abstract: Excluded. Wrong indication.

Dittrich C. (2010) Response, disease-free survival, and overall survival: What matters for whom? European Surgery - Acta Chirurgica Austriaca 42:5-7. Notes: Title/abstract: Excluded. Wrong study type.

Dixon S, Maini B, Palacios I, O'Neill W, and Gregory D. (2012) Quality of life improvements with impella hemodynamic support compared with intra-aortic balloon pump in high risk patients

receiving PCI: Results from the protect II trial. Catheterization and Cardiovascular Interventions 79:S20. Notes: Title/abstract: Excluded. Wrong study type

Dizon JM, Quinn TA, Cabreriza SE, Wang D, Spotnitz HM, Hickey K, and Garan H. (2010) Real-time stroke volume measurements for the optimization of cardiac resynchronization therapy parameters. Europace 12:1270-1274. Notes: Title/abstract: Excluded. Wrong study type.

Domingo M, Lupon J, Gonzalez B, Crespo E, Lopez R, Ramos A, Urrutia A, Pera G, Verdu JM, and Bayes-Genis A. (2011) Noninvasive remote telemonitoring for ambulatory patients with heart failure: Effect on number of hospitalizations, days in hospital, and quality of life. CARME (CAtalan Remote Management Evaluation) study. Revista Espanola de Cardiologia 64:277-285. Notes: Title/abstract: Excluded. Wrong study type.

Doyle P. (2000) To pump or not to pump? Perfusion 15:375-378. Notes: Title/abstract: Excluded. Wrong study type.

Dretzke J, Edlin R, Round J, Connock M, Hulme C, Czeczot J, Fry-Smith A, McCabe C, and Meads C. (2011) A systematic review and economic evaluation of the use of tumour necrosis factor-alpha (TNF-(alpha)) inhibitors, adalimumab and infliximab, for crohn's disease. Health Technology Assessment 15:1-250. Notes: Title/abstract: Excluded. Wrong indication.

Dyer MTD, Goldsmith KA, Sharples LS, and Buxton MJ. (2010) A review of health utilities using the EQ-5D in studies of cardiovascular disease. Health and Quality of Life Outcomes 8. Notes: Title/abstract: Included. Full text: Excluded. Review.

Eagye KJ, Kuti JL, and Nicolau DP. (2009) Risk factors and outcomes associated with isolation of meropenem high-level-resistant pseudomonas aeruginosa. Infection Control and Hospital Epidemiology 30:746-752. Notes: Title/abstract: Excluded. Wrong study type

Eckard N, Janzon M, and Levin LA. (2011) Compilation of cost-effectiveness evidence for different heart conditions and treatment strategies. Scandinavian Cardiovascular Journal 45:72-76. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Eddy DM, Schlessinger L, and Kahn R. (2005) Clinical outcomes and cost-effectiveness of strategies for managing people at high risk for diabetes. Annals of Internal Medicine 143:251-22. Notes: Title/abstract: Excluded. Wrong indication.

Eduardo Toblli J, Digennaro F, Fernando Giani J, and Pablo Dominici F. (2012) Nebivolol: Impact on cardiac and endothelial function and clinical utility. Vascular Health and Risk Management 8:151-160. Notes: Title/abstract: Excluded. Wrong study type

Ekman M, Zethraeus N, and Jonsson B. (2001) Cost effectiveness of bisoprolol in the treatment of chronic congestive heart failure in Sweden: Analysis using data from the Cardiac Insufficiency Bisoprolol Study II Trial. PharmacoEconomics 19:901-916. Notes: Title/abstract: Excluded. Wrong study type

Ekman M, Zethraeus N, Dahlstrom U, and Hoglund C. (2002) Cost-effectiveness of bisoprolol in chronic heart failure. LÃ¤kartidningen 99:646-650. Notes: Title/abstract: Excluded. Wrong study type

Ellenbogen KA, Gold MR, Meyer TE, Fernandez Lozano I, Mittal S, Waggoner AD, Lemke B, Singh JP, Spinale FG, Van Eyk JE, Whitehill J, Weiner S, Bedi M, Rapkin J, and Stein KM. (2010) Primary results from the smartdelay determined AV optimization: A comparison to other AV delay methods used in cardiac resynchronization therapy (SMART-AV) trial: A randomized trial comparing empirical, echocardiography- guided, and algorithmic atrioventricular delay programming in cardiac resynchronization therapy. Circulation 122:2660-2668. Notes: Title/abstract: Excluded. Wrong study type.

Elliott VJ, Rodgers DL, and Brett SJ. (2011) Systematic review of quality of life and other patient-centred outcomes after cardiac arrest survival. Resuscitation 82:247-256. Notes: Title/abstract: Excluded. Wrong indication

Epstein AE, DiMarco JP, Ellenbogen KA, Estes III NAM, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO, Smith J, Jacobs AK, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Faxon DP, Halperin JL, Hiratzka LF, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura RA, Ornato JP, Page RL, Riegel B, Tarkington LG, and Yancy CW. (2008) ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. Heart Rhythm 5:e1-e62. Notes: Title/abstract: Excluded. Wrong study type.

Ezekowitz JA, Thai V, Hodnefield TS, Sanderson L, and Cujec B. (2011) The correlation of standard heart failure assessment and palliative care questionnaires in a multidisciplinary heart failure clinic. Journal of Pain and Symptom Management 42:379-387. Notes: Title/abstract: Excluded. Wrong study type.

Fadol AP, Mendoza T, and Shah P. (2011) Heart failure in cancer: Is Interactive Voice Response System (IVRS) feasible for symptom management? Journal of Cardiac Failure 17:S98. Notes: Title/abstract: Excluded. Wrong study type.

Fagnani F, Litzler PY, Eltchaninoff H, Cribier A, and Banz K. (2009) Cost-effectiveness of transcatheter aortic valve implantation in high-risk patients with symptomatic aortic valve stenosis in France. Value in Health 12:A328. Notes: Title/abstract: Excluded. Wrong study type.

Farber CM and Axelrod RC. (2010) Value of rituximab for treatment of hematologic malignancies. American Journal of Pharmacy Benefits 2:360-370. Notes: Title/abstract: Excluded. Wrong study type.

Fassbender K, Fainsinger RL, Carson M, and Finegan BA. (2009) Cost Trajectories at the End of Life: The Canadian Experience. Journal of Pain and Symptom Management 38:75-80. Notes: Title/abstract: Excluded. Wrong study type.

Fattore G, Landolina M, Bontempi L, Cacciatore G, Curnis A, Gulizia M, Padeletti L, Mazzei L, and Tavazzi L. (2005) Economic impact of cardiac resynchronization therapy in heart failure patients. Available evidence and evaluation of the CRT-Eucomed model for cost-effectiveness analysis. Italian Heart Journal Supplement 6:796-803. Notes: Title/abstract: Excluded. Not in English.

Feeny D, Spritzer K, Hays RD, Liu H, Ganiats TG, Kaplan RM, Palta M, and Fryback DG. (2012) Agreement about identifying patients who change over time: cautionary results in cataract and heart failure patients. Medical decision making : an international journal of the Society for Medical Decision Making 32:273-286. Notes: Title/abstract: Excluded. Wrong study type.

Feingold B, Arora G, Webber SA, and Smith KJ. (2009) Cost-effectiveness of implantible cardioverter-defibrillators in children awaiting heart transplantation. Pediatric Transplantation 13:61. Notes: Title/abstract: Excluded. Wrong indication

Feingold B, Arora G, Webber SA, and Smith KJ. (2010) Cost-effectiveness of implantable cardioverter-defibrillators in children with dilated cardiomyopathy. Journal of Cardiac Failure 16:734-741. Notes: Title/abstract: Included. Full text: Included. Literature based estimates

Feingold BD, Arora G, Webber SA, and Smith KJ. (2009) Cost-effectiveness of implantable cardioverter-defibrillators in children with dilated cardiomyopathy. Journal of the American College of Cardiology 53:A356. Notes: Title/abstract: Excluded. Wrong study type.

Feldman AM, De Lissovoy G, Bristow MR, Saxon LA, De Marco T, Kass DA, Boehmer J, Singh S, Whellan DJ, Carson P, Boscoe A, Baker TM, and Gunderman MR. (2005) Cost effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart

Failure (COMPANION) trial. Journal of the American College of Cardiology 46:2311-2321. Notes: Title/abstract: Included. Full text: Included. Mapped from MLWHFQ

Feldman PH, Murtaugh CM, Pezzin LE, McDonald MV, and Peng TR. (2005) Just-in-time evidence-based e-mail "reminders" in home health care: Impact on patient outcomes. Health Services Research 40:865-885. Notes: Title/abstract: Excluded. Wrong study type.

Felix J, Almeida J, Joutseno J, and Alegre P. (2009) Cost-effectiveness analysis of ivabradine in chronic stable angina patients in a finnish setting. Value in Health 12:A330. Notes: Title/abstract: Excluded. Wrong study type.

Filion KB, Xie X, Van Der Avoort CJ, Dendukuri N, and Brophy JM. (2009) Microvolt T-wave alternans and the selective use of implantable cardioverter defibrillators for primary prevention: A cost-effectiveness study. International Journal of Technology Assessment in Health Care 25:151-160. Notes: Title/abstract: Excluded. Wrong indication.

Flynn KE, Lin L, Ellis SJ, Russell SD, Spertus JA, Whellan DJ, Pina IL, Fine LJ, Schulman KA, and Weinfurt KP. (2009) Outcomes, health policy, and managed care: Relationships between patient-reported outcome measures and clinical measures in outpatients with heart failure. American Heart Journal 158:S64-S71. Notes: Title/abstract: Excluded. Wrong study type.

Folke F, Lippert FK, Nielsen SL, Gislason GH, Hansen ML, Schramm TK, Sorensen R, Fosbol EL, Andersen SS, Rasmussen S, Kober L, and Torp-Pedersen C. (2009) Location of Cardiac Arrest in a City Center: Strategic Placement of Automated External Defibrillators in Public Locations. Circulation 120:510-517. Notes: Title/abstract: Excluded. Wrong study type

Ford E, Adams J, and Graves N. (2012) Development of an economic model to assess the cost-effectiveness of hawthorn extract as an adjunct treatment for heart failure in Australia. BMJ Open 2. Notes: Title/abstract: Included. Full text: Included.

Foutz RA and Sayre MR. (2000) Automated external defibrillators in long-term care facilities are cost-effective. Prehospital Emergency Care 4:314-317. Notes: Title/abstract: Excluded. Wrong study type.

Fox DJ, Davidson NC, and Fitzpatrick AP. (2007) How should we cost ICD therapy? International Journal of Cardiology 118:1-3. Notes: Title/abstract: Excluded. Wrong study type.

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: Systematic review and economic model. Health Technology Assessment 11:iii-135. Notes: Duplicate

Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, and Taylor RS. (2007) The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model. Health technology assessment (Winchester, England) 11:iii-248. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References various sources.

Frazier OH, Myers TJ, Gregoric ID, Khan T, Delgado R, Croitoru M, Miller K, Jarvik R, and Westaby S. (2002) Initial clinical experience with the Jarvik 2000 implantable axial-flow left ventricular assist system. Circulation 105:2855-2860. Notes: Title/abstract: Excluded. Wrong study type

Freemantle N and Calvert M. (2004) Answering important questions reliably - GISSI Heart Failure, a factorially designed trial with composite (co)primary outcome measures. European Journal of Heart Failure 6:531-533. Notes: Title/abstract: Excluded. Wrong study type.

Freund T, Peters-Klimm F, Rochon J, Mahler C, Gensichen J, Erler A, Beyer M, Baldauf A, Gerlach FM, and Szecsenyi J. (2011) Primary care practice-based care management for chronically ill patients (PraCMan): study protocol for a cluster randomized controlled trial [ISRCTN56104508]. Trials 12:163. Notes: Title/abstract: Excluded. Wrong study type

Freund T, Peters-Klimm F, Rochon J, Mahler C, Gensichen J, Erler A, Beyer M, Baldauf A, Gerlach FM, and Szecsenyi J. (2011) Primary care practice-based care management for chronically ill patients (PraCMan): Study protocol for a cluster randomized controlled trial [ISRCTN56104508]. Trials 12. Notes: Duplicate

Furie KL, Goldstein LB, Albers GW, Khatri P, Neyens R, Turakhia MP, Turan TN, and Wood KA. (2012) Oral antithrombotic agents for the prevention of stroke in nonvalvular atrial fibrillation: A science advisory for healthcare professionals from the American heart association/American stroke association - The American academy of neurology affirms the value of this statement as an educational tool for neurologists. Stroke 43:3442-3453. Notes: Title/abstract: Excluded. Wrong study type.

Gada H and Marwick TH. (2011) Can immediate surgery be justified by pre-operative mortality and post-operative heart failure in aortic stenosis? A decision-analytic model of survival and quality of life. Journal of the American College of Cardiology 57:E1264. Notes: Title/abstract: Excluded. Wrong study type.

Gada H, Scuffham PA, Griffin B, and Marwick TH. (2011) Quality-of-life implications of immediate surgery and watchful waiting in asymptomatic aortic stenosis. Circulation: Cardiovascular Quality and Outcomes 4:541-548. Notes: Title/abstract: Excluded. Wrong indication.

Gada H, Desai M, Sabik J, and Marwick T. (2012) Is the cost of computed tomographic angiography justified in the setting of reoperative coronary artery bypass grafting? A decision-analytic model. Journal of the American College of Cardiology 59:E1841. Notes: Title/abstract: Excluded. Wrong study type.

Gamper G, Willeit M, Sterz F, Herkner H, Zoufaly A, Hornik K, Havel C, and Laggner AN. (2004) Life after death: Posttraumatic stress disorder in survivors of cardiac arrest - Prevalence, associated factors, and the influence of sedation and analgesia. Critical Care Medicine 32:378-383. Notes: Title/abstract: Excluded. Wrong study type.

Gandjour A. (2009) Cost-effectiveness of cardioverter-defibrillators in heart failure patients. Europace 11:1721. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Garattini S. (2010) Evaluation of benefit-risk. PharmacoEconomics 28:981-986. Notes: Title/abstract: Excluded. Wrong study type.

Garcia-Perez L, Linertova R, Pinilla-Dominguez P, Davila-Ramos M, Copca-Alvarez A, Ruiz-Hernandez JJ, Diaz-Escofet M, and Escobar A. (2012) Eq-5d utilities in patients hospitalised with heart failure in canary islands. Value in Health 15:A380. Notes: Title/abstract: Excluded. Wrong study type.

Gardiner JC, Luo Z, Liu L, and Bradley CJ. (2006) A stochastic framework for estimation of summary measures in cost-effectiveness analyses. Expert Review of Pharmacoeconomics and Outcomes Research 6:347-358. Notes: Title/abstract: Excluded. Wrong study type.

Garrison J, Lubeck D, Lalla D, Paton V, Dueck A, and Perez EA. (2007) Cost-effectiveness analysis of trastuzumab in the adjuvant setting for treatment of HER2-positive breast cancer. Cancer 110:489-498. Notes: Title/abstract: Excluded. Wrong indication.

Garrison J, Wang ST, Huang H, Ba-Mancini A, Shi H, Chen K, Korves C, Dhawan R, Cakana A, van de Velde H, Corzo D, and Duh MS. (2013) The cost-effectiveness of initial treatment of multiple myeloma in the U.S. with bortezomib plus melphalan and prednisone versus thalidomide plus melphalan and prednisone or lenalidomide plus melphalan and prednisone with continuous lenalidomide maintenance treatment. Oncologist 18:27-36. Notes: Title/abstract: Excluded. Wrong indication.

Garside R, Round A, Dalziel K, Stein K, and Royle P. (2002) The effectiveness and cost-effectiveness of imatinib in chronic myeloid leukaemia: A systematic review. Health Technology Assessment 6. Notes: Title/abstract: Excluded. Wrong indication.

Garside R, Pitt M, Anderson R, Mealing S, Roome C, Snaith A, D'Souza R, Welch K, and Stein K. (2007) The effectiveness and cost-effectiveness of cinacalcet for secondary hyperparathyroidism in end-stage renal disease patients on dialysis: A systematic review and economic evaluation. Health Technology Assessment 11:iii-107. Notes: Title/abstract: Excluded. Wrong indication.

Gaziano TA. (2005) Cardiovascular disease in the developing world and its cost-effective management. Circulation 112:3547-3553. Notes: Title/abstract: Excluded. Wrong study type.

Gaziano TA, Bitton A, Anand S, Abrahams-Gessel S, and Murphy A. (2010) Growing Epidemic of Coronary Heart Disease in Low- and Middle-Income Countries. Current Problems in Cardiology 35:72-115. Notes: Title/abstract: Excluded. Wrong study type.

Gaziano TA. (2011) Are we there yet?: Steps along the way toward implementing evidence-based heart failure guidelines in middle-income countries. Circulation: Heart Failure 4:682-684. Notes: Title/abstract: Excluded. Wrong study type.

Geisberg C, Lewis C, Starmer J, Cox Z, DiSalvo T, Sawyer D, and Lenihan D. (2011) Electronic identifiers accurately identify inpatient heart failure admissions. Journal of Cardiac Failure 17:S108. Notes: Title/abstract: Excluded. Wrong study type

Geisler BP, Egan BM, Cohen JT, Garner AM, Akehurst RL, Esler MD, and Pietzsch JB. (2012) Cost-effectiveness and clinical effectiveness of catheter-based renal denervation for resistant hypertension. Journal of the American College of Cardiology 60:1271-1277. Notes: Title/abstract: Excluded. Wrong indication

Gelmon K, Chan A, and Harbeck N. (2006) The role of capecitabine in first-line treatment for patients with metastatic breast cancer. Oncologist 11:42-51. Notes: Title/abstract: Excluded. Wrong indication.

Gelsomino S, Lorusso R, Livi U, Masullo G, Luc F, Maessen J, and Gensini GF. (2011) Cost and cost-effectiveness of cardiac surgery in elderly patients. Journal of Thoracic and Cardiovascular Surgery 142:1062-1073. Notes: Title/abstract: Excluded. Wrong indication

Geocadin RG, Koenig MA, Jia X, Stevens RD, and Peberdy MA. (2008) Management of Brain Injury After Resuscitation From Cardiac Arrest. Neurologic Clinics 26:487-506. Notes: Title/abstract: Excluded. Wrong study type.

Georgiopoulou V, Azeem AA, Li S, Marti CN, Kalogeropoulos A, Dunbar SB, and Butler J. (2012) Depression symptoms evaluated by the PHQ-9 instrument in outpatients with heart failure in the atlanta cardiomyopathy consortium (TACC) study: Association with health care resource utilization and quality of life. Journal of Cardiac Failure 18:S82-S83. Notes: Title/abstract: Excluded. Wrong study type.

Gersh BJ and Block PC. (2006) Avoiding pitfalls in treating the elderly patient with angina. ACC Cardiosource Review Journal 15:38-41. Notes: Title/abstract: Excluded. Wrong study type.

Gheorghiade M, Rossi JS, Cotts W, Shin DD, Hellkamp AS, Pina IL, Fonarow GC, DeMarco T, Pauly DF, Rogers J, DiSalvo TG, Butler J, Hare JM, Francis GS, Stough WG, and O'Connor CM. (2007) Characterization and prognostic value of persistent hyponatremia in patients with severe heart failure in the ESCAPE trial. Archives of Internal Medicine 167:1998-2005. Notes: Title/abstract: Excluded. Wrong study type.

Ghosh P, Djordjevic M, Schistek R, Baier R, and Unger F. (2003) Does gender affect outcome of cardiac surgery in octogenarians? Asian Cardiovascular and Thoracic Annals 11:28-32. Notes: Title/abstract: Excluded. Wrong indication.

Giardini A, Pierobon A, Majani G, Bernocchi M, Corbellini D, and Febo O. (2012) [Perception of illness and dispositional optimism in a sample of patients with chronic heart failure]. Giornale italiano di medicina del lavoro ed ergonomia 34:B38-B44. Notes: Title/abstract: Excluded. Wrong study type.

Girling AJ, Freeman G, Gordon JP, Poole-Wilson P, Scott DA, and Lilford RJ. (2007) Modeling payback from research into the efficacy of left-ventricular assist devices as destination therapy. International Journal of Technology Assessment in Health Care 23:269-277. Notes: Title/abstract: Excluded. Wrong study type.

Gladman DD and Brown RE. (2008) Pharmacoeconomics of adalimumab for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease. Expert Review of Pharmacoeconomics and Outcomes Research 8:111-125. Notes: Title/abstract: Excluded. Wrong study type.

Glenngard AH, Borg S, Danielson BG, and Persson U. (2009) Iron deficiency in Sweden - Treatment options, costeffectiveness and reimbursement. Value in Health 12:A380. Notes: Title/abstract: Excluded. Wrong study type.

Glick H, Cook J, Kinosian B, Pitt B, Bourassa MG, Pouleur H, and Gerth W. (1995) Costs and effects of enalapril therapy in patients with symptomatic heart failure: an economic analysis of the Studies of Left Ventricular Dysfunction (SOLVD) Treatment Trial. Journal of Cardiac Failure 1:371-380. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type (uses VAS)

Glick HA, Orzol SM, Tooley JF, Remme WJ, Sasayama S, and Pitt B. (2002) Economic evaluation of the Randomized Aldactone Evaluation Study (RALES): Treatment of patients with severe heart failure. Cardiovascular Drugs and Therapy 16:53-59. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Glick 1995

Goehler A, Geisler BP, Manne JM, Jahn B, Conrads-Frank A, Schnell-Inderst P, Gazelle GS, and Siebert U. (2011) Decision-analytic models to simulate health outcomes and costs in heart failure: A systematic review. PharmacoEconomics 29:753-769. Notes: Title/abstract: Included. Full text: Excluded. Review.

Goehler A, Nolte J, Neumann A, Mostardt S, Manne JM, Abbara S, Brady TJ, Hoffmann U, Scott Gazelle G, Wasem J, and Neumann T. (2011) Clinical benefit and cost-effectiveness of cardiovascular disease screening in HIV-infected patients. Journal of the American College of Cardiology 57:E1186. Notes: Title/abstract: Excluded. Wrong study type.

Gohler A, Conrads-Frank A, Worrell SS, Geisler BP, Halpern EF, Dietz R, Anker SD, Gazelle GS, and Siebert U. (2008) Decision-analytic evaluation of the clinical effectiveness and cost-effectiveness of management programmes in chronic heart failure. European Journal of Heart Failure 10:1026-1032. Notes: Title/abstract: Included. Full text: Included. EQ-5D

Gohler A, Geisler BP, Manne JM, Kosiborod M, Zhang Z, Weintraub WS, Spertus JA, Gazelle GS, Siebert U, and Cohen DJ. (2009) Utility estimates for decision-analytic modeling in chronic heart failure - Health states based on New York Heart Association classes and number of rehospitalizations. Value in Health 12:185-187. Notes: Title/abstract: Included. Full text: Included.

Gold LS and Eisenberg M. (2007) Cost-effectiveness of automated external defibrillators in public places: Pro. Current Opinion in Cardiology 22:1-4. Notes: Title/abstract: Excluded. Wrong study type.

Goldenberg I, Moss AJ, Maron BJ, Dick AW, and Zareba W. (2005) Cost-effectiveness of implanted defibrillators in young people with inherited cardiac arrhythmias. Annals of Noninvasive Electrocardiology 10:67-83. Notes: Title/abstract: Excluded. Wrong indication

Gonzalez B, Domingo M, Lupon J, Lopez R, Ramos A, Crespo E, Urrutia A, Valenzuela J, Cano L, and Diez C. (2010) Use of telemedicine (Motiva-Philips) in an heart failure unit: Changes in patient's behaviour and impact on quality of life: The CARME study (CAtalan Remote Management

Evaluation). European Journal of Heart Failure, Supplement 9:S108. Notes: Title/abstract: Excluded. Wrong study type.

Gonzalez B, Domingo M, Lupon J, Lopez R, Ramos A, Crespo E, Urrutia A, Cano L, Diez C, and Valenzuela J. (2010) Changes in patients' behaviour and impact on quality of life with the use of telemedicine (Motiva-Philips) in an heart failure unit: the CARME study (CAtalan Remote Management Evaluation). European Heart Journal 31:233. Notes: Title/abstract: Excluded. Wrong study type

Goren A, Gupta S, and Dibonaventura MD. (2011) Health outcomes as a function of intentional and unintentional non-adherence among eleven costly conditions in the EU. Value in Health 14:A233. Notes: Title/abstract: Excluded. Wrong indication.

Goscinska-Bis K, Zupan I, Van Der H, Anselme F, Hartog H, Block M, Borri A, and Padeletti L. (2011) Predictive values for CRT response: Results from CLEAR Study. Europace 13. Notes: Title/abstract: Excluded. Wrong study type.

Grace RF, Gosley M, and Smith P. (2007) Mortality and outcomes of elderly patients admitted to the intensive care unit at Cairns Base Hospital, Australia. Critical care and resuscitation : journal of the Australasian Academy of Critical Care Medicine 9:334-337. Notes: Title/abstract: Excluded. Wrong study type.

Grady KL, Meyer PM, Dressler D, Mattea A, Chillcott S, Loo A, White-Williams C, Todd B, Ormaza S, Kaan A, Costanzo MR, and Piccione W. (2004) Longitudinal change in quality of life and impact on survival after left ventricular assist device implantation. Annals of Thoracic Surgery 77:1321-1327. Notes: Title/abstract: Excluded. Wrong indication

Graf J, Wagner J, Graf C, Koch KC, and Janssens U. (2005) Five-year survival, quality of life, and individual costs of 303 consecutive medical intensive care patients - A cost-utility analysis. Critical Care Medicine 33:547-555. Notes: Title/abstract: Excluded. Wrong indication

Graf J, Muhlhoff C, Doig GS, Reinartz S, Bode K, Dujardin R, Koch KC, Roeb E, and Janssens U. (2008) Health care costs, long-term survival, and quality of life following intensive care unit admission after cardiac arrest. Critical care (London, England) 12:R92. Notes: Title/abstract: Excluded. Wrong study type

Graf J, Muhlhoff C, Doig GS, Reinartz S, Bode K, Dujardin R, Koch KC, Roeb E, and Janssens U. (2008) Health care costs, long-term survival, and quality of life following intensive care unit admission after cardiac arrest. Critical Care 12. Notes: Duplicate

Grainger R and Harrison A. (2005) TNF inhibitors for inflammatory arthritis in New Zealand. New Zealand Medical Journal 118. Notes: Title/abstract: Excluded. Wrong study type.

Granja C, Cabral G, Pinto AT, and Costa-Pereira A. (2002) Quality of life 6-months after cardiac arrest. Resuscitation 55:37-44. Notes: Title/abstract: Excluded. Wrong indication

Gray AJ, Goodacre S, Newby DE, Masson MA, Sampson F, Dixon S, Crane S, Elliott M, and Nicholl J. (2009) A multicentre randomised controlled trial of the use of continuous positive airway pressure and non-invasive positive pressure ventilation in the early treatment of patients presenting to the emergency department with severe acute cardiogenic pulmonary oedema: The 3CPO trial. Health Technology Assessment 13:i-82. Notes: Title/abstract: Excluded. Wrong study type.

Greene HL. (2000) The implantable cardioverter-defibfillator. Clinical Cardiology 23:315-326. Notes: Title/abstract: Excluded. Wrong study type.

Gricar J and Spalding J. (2010) Cost-effectiveness of 123I-MIBG (adreview) imaging for patient treatment selection in the prevention of sudden cardiac death. Value in Health 13:A162-A163. Notes: Title/abstract: Excluded. Wrong study type.

Grima DT, Thompson MF, and Sauriol L. (2007) Modelling cost effectiveness of insulin glargine for the treatment of type 1 and 2 diabetes in Canada. PharmacoEconomics 25:253-266. Notes: Title/abstract: Excluded. Wrong indication.

Groarke J, Orfali N, Nolan P, Heerey A, Kasim S, Crowley J, Daly K, and Nash P. (2010) Cost effectiveness of Implantable Cardioverter Defibrillator (ICD) therapy in clinical practice. European Heart Journal 31:225. Notes: Title/abstract: Excluded. Wrong study type.

Groeneveld PW, Kwong JL, Liu Y, Rodriguez AJ, Jones MP, Sanders GD, and Garber AM. (2001) Cost-effectiveness of automated external defibrillators on airlines. Journal of the American Medical Association 286:1482-1489. Notes: Title/abstract: Excluded. Wrong indication

Groeneveld PW and Owens DK. (2005) Cost-effectiveness of training unselected laypersons in cardiopulmonary resuscitation and defibrillation. American Journal of Medicine 118:58-67. Notes: Title/abstract: Excluded. Wrong indication

Grosso AM, Bodalia PN, MacAllister RJ, Hingorani AD, Moon JC, and Scott MA. (2011) Comparative clinical- and cost-effectiveness of candesartan and losartan in the management of hypertension and heart failure: A systematic review, meta- and cost-utility analysis. International Journal of Clinical Practice 65:253-263. Notes: Title/abstract: Included. Full text: Excluded. Wrong health states.

Grover SA, Coupal L, and Lowensteyn I. (2007) Estimating the cost effectiveness of ramipril used for specific clinical indications: Comparing the outcomes in four clinical trials with a common economic model. American Journal of Cardiovascular Drugs 7:441-448. Notes: Title/abstract: Excluded. Wrong indication.

Gruson D and Lindberg C. (2011) Laboratory medicine: The precursors strike back. Acta Clinica Belgica 66:216-220. Notes: Title/abstract: Excluded. Wrong study type

Grzeszczak W, Czupryniak L, Kolasa K, Sciborski C, Lomon ID, and McEwan P. (2012) The cost-effectiveness of saxagliptin versus NPH insulin when used in combination with other oral antidiabetes agents in the treatment of type 2 diabetes mellitus in Poland. Diabetes Technology and Therapeutics 14:65-73. Notes: Title/abstract: Excluded. Wrong indication.

Gschwend MH, Aagren M, and Valentine WJ. (2009) Cost-effectiveness of insulin detemir compared with neutral protamine Hagedorn insulin in patients with type 1 diabetes using a basal-bolus regimen in five European countries. Journal of Medical Economics 12:114-123. Notes: Title/abstract: Excluded. Wrong indication.

Guillermin AL, Lloyd A, Best JH, Deyoung MB, Samyshkin Y, and Gaebler JA. (2012) Long-term cost-consequence analysis of exenatide once weekly vs sitagliptin or pioglitazone for the treatment of type 2 diabetes patients in the United States. Journal of Medical Economics 15:654-663. Notes: Title/abstract: Excluded. Wrong study type

Gupta M, Verma S, and Mancini GBJ. (2007) ACE inhibitors: Back to prime time? Heart 93:1015-1016. Notes: Title/abstract: Excluded. Wrong study type.

Gupta S, Gross H, and Isherwood G. (2011) The impact of high risk of stroke patients diagnosed with atrial fibrillation on health-related quality of life, and health care use in 5EU. Value in Health 14:A385. Notes: Title/abstract: Excluded. Wrong indication.

Gura V, Ronco C, Nalesso F, Brendolan A, Beizai M, Ezon C, Davenport A, and Rambod E. (2008) A wearable hemofilter for continuous ambulatory ultrafiltration. Kidney International 73:497-502. Notes: Title/abstract: Excluded. Wrong study type.

Gutzwiller FS, Blank PR, Schwenkglenks M, and Szucs TD. (2010) Health economic assessment of ferric carboxymaltose in patients with iron deficiency and chronic heart failure in the FAIR-HF trial. Value in Health 13:A353. Notes: Title/abstract: Excluded. Wrong study type.

Gutzwiller FS, Schwenkglenks M, Blank PR, Braunhofer PG, Mori C, Szucs TD, Ponikowski P, and Anker SD. (2012) Health economic assessment of ferric carboxymaltose in patients with iron deficiency and chronic heart failure based on the FAIR-HF trial: An analysis for the UK. European Journal of Heart Failure 14:782-790. Notes: Title/abstract: Excluded. Wrong indication

Guyatt GH. (1993) Measurement of health-related quality of life in heart failure. Journal of the American College of Cardiology 22:185A-191A. Notes: Title/abstract: Excluded. Wrong study type.

Gwadry-Sridhar F, Guyatt G, O'Brien B, Arnold JM, Walter S, Vingilis E, and MacKeigan L. (2008) TEACH: Trial of Education And Compliance in Heart dysfunction chronic disease and heart failure (HF) as an increasing problem. Contemporary Clinical Trials 29:905-918. Notes: Title/abstract: Excluded. Wrong study type

Hagberg LA and Lindholm L. (2006) Cost-effectiveness of healthcare-based interventions aimed at improving physical activity. Scandinavian Journal of Public Health 34:641-653. Notes: Title/abstract: Excluded. Wrong indication

Hall PS, Hulme C, McCabe C, Oluboyede Y, Round J, and Cameron DA. (2011) Updated cost-effectiveness analysis of trastuzumab for early breast cancer: A UK perspective considering duration of benefit, long-term toxicity and pattern of recurrence. PharmacoEconomics 29:415-432. Notes: Title/abstract: Excluded. Wrong indication

Hancock HC, Close H, Mason JM, Murphy JJ, Fuat A, Singh R, Wood E, De Belder M, Brennan G, Hussain N, Kumar N, Wilson D, and Hungin APS. (2013) High prevalence of undetected heart failure in long-term care residents: Findings from the Heart Failure in Care Homes (HFinCH) study. European Journal of Heart Failure 15:158-165. Notes: Title/abstract: Excluded. Wrong study type

Harrow B, Eaton CB, Assaf AR, and Sands G. (2009) Health utilities and hemoglobin levels in post menopausal women with osteoarthritis, cancer and congestive heart failure: The womens health initiative. Arthritis and Rheumatism 60:719. Notes: Title/abstract: Excluded. Wrong indication.

Harrow BS, Eaton CB, Roberts MB, Assaf AR, Luo X, and Chen Z. (2011) Health utilities associated with hemoglobin levels and blood loss in postmenopausal women: The women's health initiative. Value in Health 14:555-563. Notes: Title/abstract: Excluded. Wrong indication.

Harrow EM, Oldenburg FA, Lingenfelter MS, and Leonard J. (1992) Respiratory failure and cor pulmonale associated with tracheal mucoid accumulation from a SCOOP transtracheal oxygen catheter. Chest 101:580-581. Notes: Title/abstract: Excluded. Wrong study type

Hatzikou M, Rombopoulos G, and Yfantopoulos J. (2012) Economic evaluation of vildagliptin compared to glimepiride as add-on to metformin for the treatment of diabetes mellitus type 2 patients in Greece. Value in Health 15:A501. Notes: Title/abstract: Excluded. Wrong study type.

Havranek EP, Mcgovern KM, Weinberger J, Brocato A, Lowes BD, and Abraham WT. (1999) Patient preferences for heart failure treatment: Utilities are valid measures of health-related quality of life in heart failure. Journal of Cardiac Failure 5:85-91. Notes: Title/abstract: Included. Full text: Included. TTO

Havranek EP, Simon TA, L'Italien G, Smitten A, Brett Hauber A, Chen R, and Lapuerta P. (2004) The relationship between health perception and utility in heart failure patients in a clinical trial: Results from an OVERTURE substudy. Journal of Cardiac Failure 10:339-343. Notes: Title/abstract: Included. Full text: Included. TTO

Havranek EP and Allen LA. (2008) Listening to Patients. Journal of the American College of Cardiology 52:1709-1710. Notes: Title/abstract: Excluded. Wrong study type.

Hays RD, Kim S, Spritzer KL, Kaplan RM, Tally S, Feeny D, Liu H, and Fryback DG. (2009) Effects of mode and order of administration on generic health-related quality of life scores. Value in Health 12:1035-1039. Notes: Title/abstract: Included. Full text: Excluded. Wrong health states.

Hebert PL, Sisk JE, Wang JJ, Tuzzio L, Casabianca JM, Chassin MR, Horowitz C, and McLaughlin MA. (2008) Cost-effectiveness of nurse-led disease management for heart failure in an ethnically diverse urban community. Annals of Internal Medicine 149:540-548. Notes: Title/abstract: Included. Full text: Included. HUI3

Hebert PL and Sisk JE. (2008) Challenges facing nurse-led disease management for heart failure. Disease Management and Health Outcomes 16:1-6. Notes: Title/abstract: Excluded. Wrong study type.

Heerey A, Lauer M, AlSolaiman F, Czerr J, and James K. (2006) Cost effectiveness of biventricular pacemakers in heart failure patients. American Journal of Cardiovascular Drugs 6:129-137. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Nichol 2004.

Heflin LA, Snyder TA, Nelson KE, Long JW, and Horstmanshof DA. (2010) Time to reconsider VAD therapy? A review of mortality and quality of life in advanced heart failure clinical trials. Journal of Cardiac Failure 16:S49. Notes: Title/abstract: Excluded. Wrong indication.

Heidenreich PA, Gubens MA, Fonarow GC, Konstam MA, Stevenson LW, and Shekelle PG. (2004) Cost-effectiveness of screening with B-type natriuretic peptide to identify patients with reduced left ventricular ejection fraction. Journal of the American College of Cardiology 43:1019-1026. Notes: Title/abstract: Included. Full text: Included. Estimated from literature.

Heidenreich PA and Tsai V. (2009) Editorial: Is anyone too old for an implantable cardioverter-defibrillator? Circulation: Cardiovascular Quality and Outcomes 2:6-8. Notes: Title/abstract: Excluded. Wrong study type.

Hendrix A, Mosterd A, Doevendans P, Post J, Bots M, and Greving J. (2011) Screening for familial hypertrophic cardiomyopathy: A cost-effectiveness analysis. Fundamental and Clinical Pharmacology 25:I. Notes: Title/abstract: Excluded. Wrong indication.

Henn AJ, Tally S, Kaplan RM, Fryback D, Ganiats TG, and Sweitzer NK. (2011) Performance of generic health related quality of life instruments in heart failure clinics. Journal of Cardiac Failure 17:S84. Notes: Title/abstract: Excluded. Wrong study type

Hill JA, Pauly DF, Olitsky DR, Russell S, O'Connor CM, Patterson B, Elkayam U, Khan S, Stevenson LW, Brooks K, Wagoner L, Conway G, Koelling T, Van Huysen C, Hare J, Breton E, Adams J, Glotzer J, Fonarow G, Hamilton M, Sorg J, Drazner M, Hoffman S, Miller LW, Graziano JA, Berman ME, Frantz R, Hartman K, Leier CV, Abraham WT, Yamokoski L, DiSalvo TG, Camuso J, Gheorghiade M, Fachet K, Heroux A, Soo JK, Warnica JW, Grant J, Hasan M, Withrow L, Young J, Gus B, Butler J, Hawkins L, Rayburn BK, Robinson J, Pina I, Shelby L, Rogers J, Craddock H, Tonkon M, Miller S, DeMarco T, Lau D, Johnson M, and Ark CV. (2005) Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness. Journal of the American Medical Association 294:1625-1633. Notes: Title/abstract: Excluded. Wrong indication

Himmelfarb J. (2005) Hemodialysis complications. American Journal of Kidney Diseases 45:1122-1131. Notes: Title/abstract: Excluded. Wrong study type.

Hinchcliff ME, Carns MA, Podlusky S, Varga J, and Shah SJ. (2012) Utility of novel patient-reported outcome instruments in predicting cardiac involvement and pulmonary hypertension in patients with systemic sclerosis. Arthritis and Rheumatism 64:S307. Notes: Title/abstract: Excluded. Wrong study type.

Hind D, Ward S, De Nigris E, Simpson E, Carroll C, and Wyld L. (2007) Hormonal therapies for early breast cancer: Systematic review and economic evaluation. Health Technology Assessment 11:iii-104. Notes: Title/abstract: Excluded. Wrong indication.

Hirst NG, Whitty JA, Synnott RL, Eley DS, and Scuffham PA. (2011) Predictors of government subsidized pharmaceutical use in patients with diabetes or cardiovascular disease in a primary care

setting: Evidence from a prospective randomized trial. Journal of Medical Economics 14:698-704. Notes: Title/abstract: Excluded. Wrong study type.

Hlatky MA. (2005) Cost effectiveness of cardiac resynchronization therapy. Journal of the American College of Cardiology 46:2322-2324. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Holst M, Willenheimer R, Martensson J, Lindholm M, and Stromberg A. (2007) Telephone follow-up of self-care behaviour after a single session education of patients with heart failure in primary health care. European Journal of Cardiovascular Nursing 6:153-159. Notes: Title/abstract: Excluded. Wrong study type

Hoogendoorn M, Welsing P, and Rutten-van Molken MPMH. (2008) Cost-effectiveness of varenicline compared with bupropion, NRT, and nortriptyline for smoking cessation in the Netherlands. Current Medical Research and Opinion 24:51-61. Notes: Title/abstract: Excluded. Wrong indication.

Hozayen SM, Soliman AM, Nelson BJ, Hamel AV, and Eckman PM. (2012) Preliminary assessment of the utility of Short Performance Physical Battery (SPPB) and ferrans and power's quality of life Questionnaire (QLI) in advanced heart failure patients. Value in Health 15:A127. Notes: Title/abstract: Excluded. Wrong study type.

Hrobowski T and Lanfear DE. (2013) Ventricular assist devices: Is destination therapy a viable alternative in the non-transplant candidate? Current Heart Failure Reports 10:101-107. Notes: Title/abstract: Excluded. Wrong study type.

Hsueh WA, Orloski L, and Wyne K. (2010) Prediabetes: The importance of early identification and intervention. Postgraduate Medicine 122:129-143. Notes: Title/abstract: Excluded. Wrong study type.

Hughes M and Lip GYH. (2008) Stroke and thromboembolism in atrial fibrillation: A systematic review of stroke risk factors, risk stratification schema and cost effectiveness data. Thrombosis and Haemostasis 99:295-304. Notes: Title/abstract: Excluded. Wrong study type.

Hutchinson J, Scott DA, Clegg AJ, Loveman E, Royle P, Bryant J, and Colquitt JL. (2008) Cost-effectiveness of left ventricular-assist devices in end-stage heart failure. Expert Review of Cardiovascular Therapy 6:175-185. Notes: Title/abstract: Excluded. Wrong indication

Hutchinson MD and Mountantonakis S. (2009) Who should receive an implantable cardioverter-defibrillator after myocardial infarction? Current Heart Failure Reports 6:236-244. Notes: Title/abstract: Excluded. Wrong study type.

Hyewon HL and Levine M. (2012) Determining the threshold for acceptability of an ICER when natural health units are used. Journal of Population Therapeutics and Clinical Pharmacology 19:e234-e238. Notes: Title/abstract: Excluded. Wrong study type.

Iakovlieva L, Kyrychenko O, and Mishchenko O. (2011) Clinico-economic evaluation of complex cardiovascular therapy with magnesium orotate in patients with chronic heart failure versus standard therapy in Ukraine. Value in Health 14:A376. Notes: Title/abstract: Excluded. Wrong study type.

Icenogle TB, Sandler D, Schmitt AA, Sato D, Bjelkengren J, Schaefer SA, and Lewey S. (2012) Initial experience-cost adjusted quality of life years for patients supported by ventricular assist devices for destination therapy indication. Journal of Heart and Lung Transplantation 31:S191. Notes: Title/abstract: Excluded. Wrong indication.

Ikeda S, Imamura S, Hashimoto I, Morioka S, Sakuma M, and Ogawa H. (2003) History of the establishment and revision of diagnostic criteria, severity index and therapeutic guidelines for pemphigus in Japan. Archives of Dermatological Research, Supplement 295:S12-S16. Notes: Title/abstract: Excluded. Wrong study type

Inada K, Roberts-Thomson KC, Seiler J, Steven D, Tedrow UB, Koplan BA, and Stevenson WG. (2010) Mortality and safety of catheter ablation for antiarrhythmic drug-refractory ventricular tachycardia in elderly patients with coronary artery disease. Heart Rhythm 7:740-744. Notes: Title/abstract: Excluded. Wrong study type.

Ines M, Soares M, and Vitorino R. (2010) Cost-effectiveness of eplerenone compared with spironolactone in patients with heart failure after acute myocardial infarction. Value in Health 13:A354. Notes: Title/abstract: Excluded. Wrong study type.

Ingles J, Yeates L, Hunt L, McGaughran J, Scuffham P, Atherton J, and Semsarian C. (2011) Health status of cardiac genetic disease patients and their at-risk relatives. Heart Lung and Circulation 20:S220. Notes: Title/abstract: Excluded. Wrong study type

Ingles J, Yeates L, Hunt L, McGaughran J, Scuffham PA, Atherton J, and Semsarian C. (2011) Health status of cardiac genetic disease patients and their at-risk relatives. International Journal of Cardiology. Notes: Title/abstract: Excluded. Wrong indication

Iskander S and Iskandrian AE. (1999) Prognostic utility of myocardial viability assessment. American Journal of Cardiology 83:696-702. Notes: Title/abstract: Excluded. Wrong study type.

Ito K, Shrank WH, Avorn J, Patrick AR, Brennan TA, Antman EM, and Choudhry NK. (2012) Comparative Cost-Effectiveness of Interventions to Improve Medication Adherence after Myocardial Infarction. Health Services Research 47:2097-2117. Notes: Title/abstract: Excluded. Wrong indication

Jamieson MJ and Jamieson C. (2001) Ambulatory blood pressure in heart failure. European Journal of Clinical Investigation, Supplement 31:18-25. Notes: Title/abstract: Excluded. Wrong study type.

Jansen JP, Gaugris S, Choy EH, Ostor A, Nash JT, and Stam W. (2010) Cost Effectiveness of Etoricoxib Versus Celecoxib and Non-Selective NSAIDS in the Treatment of Ankylosing Spondylitis. PharmacoEconomics 28:323-344. Notes: Title/abstract: Excluded. Wrong indication

Jansen JP and Taylor SD. (2011) Cost-effectiveness evaluation of etoricoxib versus celecoxib and nonselective nsaids in the treatment of ankylosing spondylitis in norway. International Journal of Rheumatology 2011. Notes: Title/abstract: Excluded. Wrong indication

Janssen DJ, Franssen FM, Wouters EF, Schols JM, and Spruit MA. (2011) Impaired health status and care dependency in patients with advanced COPD or chronic heart failure. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation 20:1679-1688. Notes: Title/abstract: Included. Full text: Included. EQ-5D and AQoL

Janssen DJA, Spruit MA, Schols JMGA, Cox B, Nawrot TS, Curtis JR, and Wouters EFM. (2012) Predicting changes in preferences for life-sustaining treatment among patients with advanced chronic organ failure. Chest 141:1251-1259. Notes: Title/abstract: Excluded. Wrong indication

Janssen MF, Lubetkin EI, Sekhobo JP, and Pickard AS. (2011) The use of the EQ-5D preference-based health status measure in adults with Type 2 diabetes mellitus. Diabetic Medicine 28:395-413. Notes: Title/abstract: Excluded. Wrong indication.

Jaworska E, Wlodarczyk A, and Budasz-Swiderska M. (2012) Clinical and cost-effectiveness of third-generation, implantable left ventricular assist devices for people with end-stage heart failure: A systematic review. Value in Health 15:A345. Notes: Title/abstract: Excluded. Wrong study type.

Jo MW, Kim SH, Choi Y, and Kim J. (2010) Cost-effectiveness of dronedarone in South Korea. Value in Health 13:A356. Notes: Title/abstract: Excluded. Wrong study type.

Joshi R, Lopez AD, MacMahon S, Reddy S, Dandona R, Dandona L, and Neal B. (2009) Verbal autopsy coding: Are multiple coders better than one? Bulletin of the World Health Organization 87:51-57. Notes: Title/abstract: Excluded. Wrong study type.

Jurgens CY, Faulkner KM, and Lee CS. (2013) Phenotypic profiling of cognitive impairment risk among patients with heart failure: A literature review of the usefulness of cardiac-related variables. European Journal of Cardiovascular Nursing 12:109-131. Notes: Title/abstract: Excluded. Wrong study type

Kamath GS and Mittal S. (2008) The Role of Antiarrhythmic Drug Therapy for the Prevention of Sudden Cardiac Death. Progress in Cardiovascular Diseases 50:439-448. Notes: Title/abstract: Excluded. Wrong study type.

Kantu M, Judkins J, and Shulman A. (1999) Tracheostomy for ventilator dependence in the elderly patient: A preliminary report. Ear, Nose and Throat Journal 78:500-504. Notes: Title/abstract: Excluded. Wrong study type.

Kaplan RM, Tally S, Hays RD, Feeny D, Ganiats TG, Palta M, and Fryback DG. (2011) Five preference-based indexes in cataract and heart failure patients were not equally responsive to change. Journal of Clinical Epidemiology 64:497-506. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type (looks at correlations)

Karnon J. (2007) Cost-effectiveness of letrozole, anastrozole and exemestane for early adjuvant breast cancer. Expert Review of Pharmacoeconomics and Outcomes Research 7:143-153. Notes: Title/abstract: Excluded. Wrong indication.

Karnon J, Delea T, and Barghout V. (2008) Cost utility analysis of early adjuvant letrozole or anastrozole versus tamoxifen in postmenopausal women with early invasive breast cancer: The UK perspective. European Journal of Health Economics 9:171-183. Notes: Title/abstract: Excluded. Wrong indication.

Kasprzak JD, Kaczmarek M, Fiutowski M, Bednarkiewicz Z, Wcislo T, and Krzeminska-Pakula M. (2009) Determinants of quality of life in cardioverter-defibrillator recipients: A nurse-led study. European Heart Journal 30:3. Notes: Title/abstract: Excluded. Wrong study type.

Kavanagh T, Myers MG, Baigrie RS, Mertens DJ, Sawyer P, and Shephard RJ. (1996) Quality of life and cardiorespiratory function in chronic heart failure: Effects of 12 months' aerobic training. Heart 76:42-49. Notes: Title/abstract: Included. Full text: Excluded. Insufficinet detail

Kavanaugh A, Cohen S, and Cush JJ. (2004) The evolving use of tumor necrosis factor inhibitors in rheumatoid arthritis. Journal of Rheumatology 31:1881-1884. Notes: Title/abstract: Excluded. Wrong study type.

Kazi DS and Mark DB. (2013) The Economics of Heart Failure. Heart Failure Clinics 9:93-106. Notes: Title/abstract: Excluded. Wrong study type.

Keech A and Horowitz JD. (2009) Cost-effectiveness Considerations of Cardiovascular Therapeutics. Heart Lung and Circulation 18:118-122. Notes: Title/abstract: Excluded. Wrong study type

Kellett J. (2005) How many patients in atrial fibrillation admitted to an acute medical unit will benefit from oral anticoagulation? Application of the results of the major randomized controlled trials to 141 consecutive, unselected, elderly patients using a decision support computer program. European Journal of Internal Medicine 16:97-104. Notes: Title/abstract: Excluded. Wrong study type.

Kelsall D. (2011) Clinical shorts. CMAJ 183:1623. Notes: Title/abstract: Excluded. Wrong study type.

Kirklin JK, McGiffin DC, Pinderski LJ, and Tallaj J. (2004) Selection of patients and techniques of heart transplantation. Surgical Clinics of North America 84:257-287. Notes: Title/abstract: Excluded. Wrong study type.

Kirkpatrick JN. (2010) ABCD's of heart failure: Echo-ing through the first stage. Journal of the American Society of Echocardiography 23:1035-1038. Notes: Title/abstract: Excluded. Wrong study type.

Klepanec A, Mistrik M, Altaner C, Valachovicova M, Olejarova I, Slysko R, Balazs T, Urlandova T, Hladikova D, Liska B, Tomka J, Vulev I, and Madaric J. (2012) No difference in intra-arterial and intramuscular delivery of autologous bone marrow cells in patients with advanced critical limb ischemia. Cell Transplantation 21:1909-1918. Notes: Title/abstract: Excluded. Wrong study type.

Klersy C, De Silvestri A, Gabutti G, Raisaro A, Curti M, Regoli F, and Auricchio A. (2011) Economic impact of remote patient monitoring: An integrated economic model derived from a meta-analysis of randomized controlled trials in heart failure. European Journal of Heart Failure 13:450-459. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Hebert 2008

Kontodimopoulos N, Argiriou M, Theakos N, and Niakas D. (2009) Assessing the (DIS) agreement of EQ-5D and SF-6D across groups with increasing severity of chronic heart failure. Value in Health 12:A396. Notes: Title/abstract: Excluded. Wrong study type.

Kontodimopoulos N, Argiriou M, Theakos N, and Niakas D. (2011) The impact of disease severity on EQ-5D and SF-6D utility discrepancies in chronic heart failure. European Journal of Health Economics 12:383-391. Notes: Title/abstract: Included. Full text: Included.

Krause T, Lovibond K, Caulfield M, McCormack T, and Williams B. (2011) Management of hypertension: Summary of NICE guidance. BMJ (Online) 343. Notes: Title/abstract: Excluded. Wrong study type

Krown SE, Northfelt DW, Osoba D, and Stewart JS. (2004) Use of liposomal anthracyclines in Kaposi's sarcoma. Seminars in Oncology 31:36-52. Notes: Title/abstract: Excluded. Wrong study type.

Kruger T, Brandenburg V, Schlieper G, Marx N, and Floege J. (2013) Sailing between Scylla and Charybdis: Oral long-term anticoagulation in dialysis patients. Nephrology Dialysis Transplantation 28:534-541. Notes: Title/abstract: Excluded. Wrong study type.

Krum H. (2000) New and emerging pharmacologic strategies in the management of chronic heart failure. Clinical Cardiology 23:724-730. Notes: Title/abstract: Excluded. Wrong study type.

Kuhr EM, Ribeiro RA, Rohde LE, Beck da Silva LN, Clausell NO, Ribeiro JP, and Polanczyk CA. (2009) Cost-effectiveness of an exercise training program in heart failure. Value in Health 12:A329-A330. Notes: Title/abstract: Excluded. Wrong study type.

Kuhr EM, Ribeiro RA, Rohde LEP, and Polanczyk CA. (2011) Cost-effectiveness of supervised exercise therapy in heart failure patients. Value in Health 14:S100-S107. Notes: Duplicate

Kuhr EM, Ribeiro RA, Rohde LEP, and Polanczyk CA. (2011) Cost-effectiveness of supervised exercise therapy in heart failure patients. Value in Health 14:S100-S107. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. Reference Gohler 2009

Kuilman M, Bleeker JK, Hartman JAM, and Simoons ML. (1999) Long-term survival after out-of-hospital cardiac arrest: An 8-year follow-up. Resuscitation 41:25-31. Notes: Title/abstract: Excluded. Wrong study type

Kupersmith J. (2002) The past, present, and future of the implantable cardioverter defibrillator. American Journal of Medicine 112:577-579. Notes: Title/abstract: Excluded. Wrong study type.

Kurian AW, Thompson RN, Gaw AF, Arai S, Ortiz R, and Garber AM. (2007) A cost-effectiveness analysis of adjuvant trastuzumab regimens in early HER2/neu-positive breast cancer. Journal of Clinical Oncology 25:634-641. Notes: Title/abstract: Excluded. Wrong indication.

Kutyifa V, Aidelsburger P, Schauer S, Merkely B, Klein H, Kuniss M, Kloppe A, Kayser T, Peppa R, and Moss AJ. (2012) Cost-effectiveness of cardiac resynchronization therapy in combination with an implantable cardioverter defibrillator in mild heart failure based on Markov modeling using UK cost approach in MADIT CRT. European Heart Journal 33:896. Notes: Title/abstract: Excluded. Conference abstract.

Laiteerapong N, John PM, Meltzer DO, and Huang ES. (2011) Estimating the health effects of different delays in achieving systolic blood pressure control in adults with diabetes. Journal of General Internal Medicine 26:S223-S224. Notes: Title/abstract: Excluded. Wrong indication.

Lamond NWD, Skedgel C, Rayson D, Lethbridge L, and Younis T. (2012) Cost-utility of the 21-gene recurrence score assay in node-negative and node-positive breast cancer. Breast Cancer Research and Treatment 133:1115-1123. Notes: Title/abstract: Excluded. Wrong indication.

Laramee P, Wonderling D, Swain S, Al-Mohammad A, and Mant J. (2013) Cost-effectiveness analysis of serial measurement of circulating natriuretic peptide concentration in chronic heart failure. Heart 99:267-271. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. Reference Gohler 2009

Lee,AJ and P McCluskey. Clinical utility and differential effects of prostaglandin analogs in the management of raised intraocular pressure and ocular hypertension. Clinical Ophthalmology 4[1], 741-764. 2010. Ref Type: Generic Notes: Title/abstract: Excluded. Wrong study type

Lee CS, Kim AY, Green J, and Rosenfeld A. (2011) Symptom profiles in advanced heart failure with marked differences in quality-of-life. Journal of Cardiac Failure 17:S76. Notes: Title/abstract: Excluded. Wrong study type

Lee CS, Green J, Rosenfeld AG, and Kim AY. (2011) Physical and psychological symptom profiles predict poor quality-of-life in advanced heart failure. Circulation 124. Notes: Title/abstract: Excluded. Wrong study type

Lee KH, Angus DC, and Abramson NS. (1996) Cardiopulmonary resuscitation: What cost to cheat death? Critical Care Medicine 24:2046-2052. Notes: Title/abstract: Excluded. Wrong study type.

Leff JD and Shore-Lesserson L. (2010) Left ventricular assist devices: An evolving state of the art. Seminars in Cardiothoracic and Vascular Anesthesia 14:21-23. Notes: Title/abstract: Excluded. Wrong study type

Lehmann DF and Medicis JJ. (1998) A pharmacoeconomic model to aid in the allocation of ambulatory clinical pharmacy services. Journal of Clinical Pharmacology 38:783-791. Notes: Title/abstract: Excluded. Wrong study type.

Leidy NK, Rentz AM, and Zyczynski TM. (1999) Evaluating health-related quality-of-life outcomes in patients with congestive heart failure: A review of recent randomised controlled trials. PharmacoEconomics 15:19-46. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Leontiadis GI, Sreedharan A, Dorward S, Barton P, Delaney B, Howden CW, Orhewere M, Gisbert J, Sharma VK, Rostom A, Moayyedi P, and Forman D. (2007) Systematic reviews of the clinical effectiveness and cost-effectiveness of proton pump inhibitors in acute upper gastrointestinal bleeding. Health Technology Assessment 11:iii-126. Notes: Title/abstract: Excluded. Wrong indication.

Lerner EB, Maio RF, Garrison HG, Spaite DW, and Nichol G. (2006) Economic Value of Out-of-Hospital Emergency Care: A Structured Literature Review. Annals of Emergency Medicine 47:515-524. Notes: Title/abstract: Excluded. Wrong study type.

Lewis EF, Johnson PA, Johnson W, Collins C, Griffin L, and Stevenson LW. (2001) Preferences for quality of life or survival expressed by patients with heart failure. Journal of Heart and Lung Transplantation 20:1016-1024. Notes: Title/abstract: Included. Full text: Excluded. Wrong health states.

Lewis R, Bagnall AM, King S, Woolacott N, Forbes C, Shirran L, Duffy S, Kleijnen J, Ter Riet G, and Riemsma R. (2002) The clinical effectiveness and cost-effectiveness of vinorelbine for breast cancer: A systematic review and economic evaluation. Health Technology Assessment 6. Notes: Title/abstract: Excluded. Wrong indication

Li H and Heitjan DF. (2006) A pattern-mixture model for the analysis of censored quality-of-life data. Statistics in Medicine 25:1533-1546. Notes: Title/abstract: Excluded. Wrong study type.

Li Y, Whellan DJ, Samsa GP, Schulman K, and Reed SD. (2010) Discriminatory power of the KCCQ in estimating health utilities in heart failure patients. Value in Health 13:A170. Notes: Title/abstract: Excluded. Wrong study type.

Li Y, Neilson M, Whellan DJ, Schulman KA, Levy WC, and Reed SD. (2012) Seattle heart failure model scores are significantly predictive of health utilities and their change over time. Journal of Cardiac Failure 18:S81. Notes: Title/abstract: Excluded. Wrong study type.

Liang KV, Pike F, Argyropoulos C, Weissfeld L, Teuteberg J, Dew MA, and Unruh ML. (2011) Heart failure severity scoring system and medical- and health-related quality-of-life outcomes: The HEMO study. American Journal of Kidney Diseases 58:84-92. Notes: Title/abstract: Excluded. Wrong indication.

Lidgren M, Jonsson B, Rehnberg C, Willking N, and Bergh J. (2008) Cost-effectiveness of HER2 testing and 1-year adjuvant trastuzumab therapy for early breast cancer. Annals of Oncology 19:487-495. Notes: Title/abstract: Excluded. Wrong indication.

Lim GB. (2013) Public health: Global burden of cardiovascular disease. Nature Reviews Cardiology 10:59. Notes: Title/abstract: Excluded. Wrong study type.

Linde C, Mealing S, Hawkins N, Eaton J, Brown B, and Daubert C. (2010) Cost-effectiveness evaluation of CRT in patients with asymptomatic or mildly symptomatic left ventricular dysfunction based on the 24 month outcomes from the European cohort. European Heart Journal 31:12. Notes: Title/abstract: Excluded. Wrong study type.

Linde C, Mealing S, Hawkins N, Eaton J, Brown B, and Daubert JC. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure: Insights from the European cohort of the REVERSE (Resynchronization Reverses remodeling in Systolic Left Ventricular Dysfunction). European Heart Journal 32:1631-1639. Notes: Title/abstract: Included. Full text: Included. Literature base estimates

Lindsay TF and Dueck AD. (2006) Is duplex surveillance of value after leg vein bypass grafting? Vascular Medicine 11:137-138. Notes: Title/abstract: Excluded. Wrong study type.

Ling L, Ellims A, Lee G, Teh A, Medi C, Kaye D, Tayor A, and Kistler P. (2011) Late gadolinium enhancement on cardiac MRI predicts response to atrial fibrillation ablation in patients with heart failure. Heart Lung and Circulation 20:S100. Notes: Title/abstract: Excluded. Wrong study type.

Littlejohn C and Crilly MA. (2012) Industry-sponsored cost-effectiveness study of TAVI. Heart 98:1258. Notes: Title/abstract: Excluded. Wrong study type

Lloyd-Williams F, Mair FS, and Leitner M. (2002) Exercise training and heart failure: A systematic review of current evidence. British Journal of General Practice 52:47-55. Notes: Title/abstract: Excluded. Wrong study type.

Longstreth WT, Nichol G, Van Ottingham L, and Hallstrom AP. (2010) Two simple questions to assess neurologic outcomes at 3 months after out-of-hospital cardiac arrest: Experience from the Public Access Defibrillation Trial. Resuscitation 81:530-533. Notes: Title/abstract: Excluded. Wrong indication

Lopes G and Dent R. (2011) Weighed, measured, and still searching: Bevacizumab in the treatment of unselected patients with advanced breast cancer. Oncologist 16:1669-1671. Notes: Title/abstract: Excluded. Wrong study type.

Lopez-Sendon JL, Marti-Sanchez D, Marti B, Oyaguez I, and Casado MA. (2011) Cost-effective analysis of eplerenone in patients with post-acute myocardial infarction heart failure. Pharmacoeconomics - Spanish Research Articles 8:39-50. Notes: Title/abstract: Excluded. Wrong indication

Lopez Cabezas C, Falces Salvador C, Cubi Quadrada D, Arnau Bartes A, Ylla Bore M, Muro Perea N, and Homs Peipoch E. (2006) Randomized clinical trial of a postdischarge pharmaceutical care program vs. regular follow-up in patients with heart failure. Farmacia Hospitalaria 30:328-342. Notes: Title/abstract: Excluded. Wrong study type.

Loughran JH, Chugh AR, Ismail I, and Bolli R. (2013) Stem cell therapy: Promising treatment in heart failure? Current Heart Failure Reports 10:73-80. Notes: Title/abstract: Excluded. Wrong study type.

Luangasanatip N, Chaiyakunapruk N, Upakdee N, and Wong P. (2011) Iron-chelating therapies in a transfusion-dependent thalassaemia population in Thailand: A cost-effectiveness study. Clinical Drug Investigation 31:493-505. Notes: Title/abstract: Excluded. Wrong indication

Lucignani G. (2009) Metaiodobenzylguanidine (mIBG) molecular imaging in implantable cardioverter defibrillator (ICD) therapy planning: A health technology assessment issue. European Journal of Nuclear Medicine and Molecular Imaging 36:1346-1350. Notes: Title/abstract: Excluded. Wrong study type

Luo X, Cappelleri JC, and Chandran A. (2011) The Burden of Fibromyalgia: Assessment of Health Status Using the EuroQol (EQ-5D) in Patients with Fibromyalgia Relative to Other Chronic Conditions. Health Outcomes Research in Medicine. Notes: Title/abstract: Excluded. Wrong indication.

Luo X, Cappelleri JC, and Chandran A. (2011) The burden of fibromyalgia: Assessment of health status using the EuroQol (EQ-5D) in patients with fibromyalgia relative to other chronic conditions. Health Outcomes Research in Medicine 2:e203-e214. Notes: Duplicate

Luo X, Cappelleri JC, and Chandran A. (2011) The burden of fibromyalgia: Assessment of health status using the euroqol (EQ 5D in patients with fibromyalgia relative to other chronic conditions. Pain Medicine 12:477-478. Notes: Title/abstract: Excluded. Wrong indication.

Lyseng-Williamson KA and Foster RH. (2004) Infliximab: A Pharmacoeconomic Review of its Use in Rheumatoid Arthritis. PharmacoEconomics 22:107-132. Notes: Title/abstract: Excluded. Wrong indication

Machiraju VR. (2004) How to avoid problems in redo coronary artery bypass surgery. Journal of Cardiac Surgery 19:284-290. Notes: Title/abstract: Excluded. Wrong study type.

Macias-Gallego A and Ruiz-Granell R. (2005) Cardiac resynchronization therapy: An economic perspective. Revista Espanola de Cardiologia Suplementos 5:18B-23B. Notes: Title/abstract: Excluded. Wrong study type.

MacK MJ. (2011) In-hospital outcomes of very elderly patients (85 years and older) undergoing percutaneous coronary intervention. Catheterization and Cardiovascular Interventions 77:642. Notes: Title/abstract: Excluded. Wrong study type.

Magnuson EA, Farkouh ME, Fuster V, Wang K, Vilain K, Li H, Appelwick J, Muratov V, Sleeper LA, Boineau R, Abdallah M, and Cohen DJ. (2013) Cost-effectiveness of percutaneous coronary intervention with drug eluting stents versus bypass surgery for patients with diabetes mellitus and multivessel coronary artery disease: Results from the FREEDOM trial. Circulation 127:820-831. Notes: Title/abstract: Excluded. Wrong indication.

Mahle WT, Forbess JM, Kirshbom PM, Cuadrado AR, Simsic JM, and Kanter KR. (2005) Cost-utility analysis of salvage cardiac extracorporeal membrane oxygenation in children. Journal of Thoracic and Cardiovascular Surgery 129:1084-1090. Notes: Title/abstract: Excluded. Wrong indication

Maini B, O'Neill W, Dixon S, Palacios I, Schreiber T, Gregory DA, and Scotti DJ. (2011) Cost-effectiveness and clinical outcomes of impella hemodynamic support compared with intra-aortic balloon pump in high risk patients receiving PCI: Results from the PROTECT II trial. Journal of the American College of Cardiology 58:B131-B132. Notes: Title/abstract: Excluded. Wrong indication

Maini BS, O'Neill W, Palacios I, Dixon S, and Gregory D. (2012) Cost-effectiveness and quality of life improvements: Impella hemodynamic support compared with intra-aortic balloon pump in high risk patients receiving PCI. Journal of the American College of Cardiology 59:E68. Notes: Title/abstract: Excluded. Wrong indication.

Maisel AS, Nakao K, Ponikowski P, Peacock WF, Yoshimura M, Suzuki T, Tsutamoto T, Filippatos GS, Saito Y, Seino Y, Minamino N, Hirata Y, Mukoyama M, Nishikimi T, and Nagai R. (2011) Japanese-western consensus meeting on biomarkers executive summary. International Heart Journal 52:253-265. Notes: Title/abstract: Excluded. Wrong study type

Maniadakis N, Ekman M, Fragoulakis V, Papagiannopoulou V, and Yfantopoulos J. (2011) Economic evaluation of irbesartan in combination with hydrochlorothiazide in the treatment of hypertension in Greece. European Journal of Health Economics 12:253-261. Notes: Title/abstract: Excluded. Wrong indication

Maniadakis N, Ekman M, Calvert MJ, Freemantle N, Karamalis M, and Vardas P. (2011) Cost effectiveness of cardiac resynchronization therapy in Greece: An analysis based on the CArdiac REsychronization in Heart Failure trial. Europace 13:1597-1603. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Calvert 2005.

Manji RA, Witt J, and Menkis AH. (2011) It is cost-effective to give a short course of low dose prophylactic steroids to cardiac surgery ICU patients at medium to high risk for postoperative atrial fibrillation. Canadian Journal of Cardiology 27:S288-S289. Notes: Title/abstract: Excluded. Wrong indication.

Manji RA, Witt J, and Menkis AH. (2012) Is it more cost-effective to use steroids or colchicine in patients at moderate to high risk for atrial fibirillation to prevent post-cardiac surgery atrial fibrillation? Canadian Journal of Cardiology 28:S384-S385. Notes: Title/abstract: Excluded. Wrong indication.

Mark DB, Nelson CL, Anstrom KJ, Al-Khatib SM, Tsiatis AA, Cowper PA, Clapp-Channing NE, Davidson-Ray L, Poole JE, Johnson G, Anderson J, Lee KL, and Bardy GH. (2006) Cost-effectiveness of defibrillator therapy or amiodarone in chronic stable heart failure: Results from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Circulation 114:135-142. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Nichol 2004.

Mark DB, Knight JD, Cowper PA, Davidson-Ray L, and Anstrom KJ. (2008) Long-term economic outcomes associated with intensive versus moderate lipid-lowering therapy in coronary artery disease: Results from the Treating to New Targets (TNT) Trial. American Heart Journal 156:698-705. Notes: Title/abstract: Excluded. Wrong indication

Mark DB. (2009) The author replies. New England Journal of Medicine 360:189. Notes: Title/abstract: Excluded. Wrong study type.

Marks JB. (2005) Addressing end-of-life issues. Clinical Diabetes 23:98-99. Notes: Title/abstract: Excluded. Wrong study type.

Marwick TH and Hunink M. (2009) Timing of operation in asymptomatic mitral regurgitation: A decision analytic model of quality of life and cost. Journal of the American College of Cardiology 53:A417. Notes: Title/abstract: Excluded. Wrong study type.

Marwick TH, Scuffham PA, and Hunink MGM. (2011) Selection for early surgery in asymptomatic mitral regurgitation: A Markov model. International Journal of Cardiology. Notes: Title/abstract: Excluded. Wrong indication.

Mason C and Dunnill P. (2008) The strong financial case for regenerative medicine and the regen industry. Regenerative Medicine 3:351-363. Notes: Title/abstract: Excluded. Wrong study type.

Mason J, Eccles M, Freemantle N, and Drummond M. (1999) A framework for incorporating cost-effectiveness in evidence-based clinical practice guidelines. Health Policy 47:37-52. Notes: Title/abstract: Excluded. Wrong study type.

Matlock DD. (2009) Defibrillators in heart failure and quality of life. New England Journal of Medicine 360:187-188. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Maxwell CJ, Kang J, Walker JD, Zhang JX, Hogan DB, Feeny DH, and Wodchis WP. (2009) Sex differences in the relative contribution of social and clinical factors to the health utilities index mark 2 measure of health-related quality of life in older home care clients. Health and Quality of Life Outcomes 7:80. Notes: Title/abstract: Excluded. Wrong indication

Mayer J. (2012) Transcatheter aortic valve implantation should be controlled and monitored by the medical profession. Journal of Thoracic and Cardiovascular Surgery 143:771-773. Notes: Title/abstract: Excluded. Wrong study type.

McAlister FA, Ezekowitz J, Hooton N, Vandermeer B, Spooner C, Dryden DM, Page RL, Hlatky MA, and Rowe BH. (2007) Cardiac resynchronization therapy for patients with left ventricular systolic dysfunction: A systematic review. Journal of the American Medical Association 297:2502-2514. Notes: Title/abstract: Excluded. Wrong study type.

McKenna C, McDaid C, Suekarran S, Hawkins N, Claxton K, Light K, Chester M, Cleland J, Woolacott N, and Sculpher M. (2009) Enhanced external counterpulsation for the treatment of stable angina and heart failure: A systematic review and economic analysis. Health Technology Assessment 13:ix-112. Notes: Title/abstract: Excluded. Wrong indication

McKenna C, McDaid C, Suekarran S, Hawkins N, Claxton K, Light K, Chester M, Cleland J, Woolacott N, and Sculpher M. (2009) Enhanced external counterpulsation for the treatment of stable angina and heart failure: a systematic review and economic analysis. Health technology assessment (Winchester, England) 13:iii-xi, 1. Notes: Duplicate

McKenna C, Burch J, Suekarran S, Walker S, Bakhai A, Witte K, Harden M, Wright K, Woolacott N, Lorgelly P, Fenwick L, and Palmer S. (2010) A systematic review and economic evaluation of the clinical effectiveness and cost-effectiveness of aldosterone antagonists for postmyocardial infarction heart failure. Health technology assessment (Winchester, England) 14:1-162. Notes: Title/abstract: Excluded. Wrong indication.

McKenna C, Burch J, Suekarran S, Walker S, Bakhai A, Witte K, Harden M, Wright K, Woolacott N, Lorgelly P, Fenwick L, and Palmer S. (2010) A systematic review and economic evaluation of the clinical effectiveness and cost-effectiveness of aldosterone antagonists for postmyocardial infarction heart failure. Health Technology Assessment 14:i-161. Notes: Duplicate

McKenna C, Walker S, Lorgelly P, Fenwick E, Burch J, Suekarran S, Bakhai A, Witte K, Harden M, Wright K, Woolacott N, and Palmer S. (2012) Cost-effectiveness of aldosterone antagonists for the treatment of post-myocardial infarction heart failure. Value in Health 15:420-428. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Goehler 2009

McLeod C, Bagust A, Boland A, Dagenais P, Dickson R, Dundar Y, Hill RA, Jones A, Mujica Mota R, and Walley T. (2007) Adalimumab, etanercept and infliximab for the treatment of ankylosing spondylitis: A systematic review and economic evaluation. Health Technology Assessment 11:1-113. Notes: Title/abstract: Excluded. Wrong indication

Mcmanus J, Boyce F, Page J, Martin J, Murray L, and Taylor J. (2009) Is exercise training feasible for elderly heart failure patients within a day hospital setting? A pilot study. European Journal of Heart Failure, Supplement 8:ii632. Notes: Title/abstract: Excluded. Wrong study type.

McMurray J. (1999) The health economics of the treatment of hyperlipidemia and hypertension. American Journal of Hypertension 12:99S-104S. Notes: Title/abstract: Excluded. Wrong study type.

McNeil FM, Lee CS, Song HK, Kim AY, and Rosenfeld A. (2012) Quality of life is higher in destination therapy compared with bridge to transplantation patients following ventricular assist device implantation. Journal of Heart and Lung Transplantation 31:S19. Notes: Title/abstract: Excluded. Wrong study type

McQueen MJ, Lonn E, Gerstein HC, Bosch J, and Yusuf S. (2005) The HOPE (Heart Outcomes Prevention Evaluation) study and its consequences. Scandinavian Journal of Clinical and Laboratory Investigation 65:143-156. Notes: Title/abstract: Excluded. Wrong indication.

Mealing S and Eaton JN. (2011) MitraClip for patients with mitral regurgitation who are ineligible for surgical repair or replacement: A uk based cost-utility analysis. Journal of the American College of Cardiology 58:B212. Notes: Title/abstract: Excluded. Wrong indication.

Meine M, Smith T, and Hauer RNW. (2009) The economical challenge in the treatment of chronic heart failure: Is primary prophylactic ICD therapy cost-effective in europe? Europace 11:689-691. Notes: Title/abstract: Excluded. Wrong study type.

Meine M, Smith T, and Hauer RNW. (2009) The economical challenge in the treatment of chronic heart failure: Is primary prophylactic ICD therapy cost-effective in Europe? Reply. Europace 11:1408-1410. Notes: Duplicate

Mejia A, Richardson G, Cockayne S, Pattenden J, and Lewin R. (2012) Cost-effectiveness of a nurse facilitated self-management programme for heart failure. Value in Health 15:A281. Notes: Title/abstract: Excluded. Wrong study type.

Mell HK and Sayre MR. (2008) Public Access Defibrillators and Fire Extinguishers: Are Comparisons Reasonable? Progress in Cardiovascular Diseases 51:204-212. Notes: Title/abstract: Excluded. Wrong study type.

Merchant RM, Becker LB, Abella BS, Asch DA, and Groeneveld PW. (2009) Cost-effectiveness of therapeutic hypothermia after cardiac arrest. Circulation: Cardiovascular Quality and Outcomes 2:421-428. Notes: Title/abstract: Excluded. Wrong indication

Meredith PA and Jarvis SC. (2011) Comments on systematic review of clinical- and cost-effectiveness of candesartan and losartan in hypertension and heart failure. International Journal of Clinical Practice 65:911. Notes: Title/abstract: Excluded. Wrong study type

Miljoen H, Siebens K, Vrints C, and Denollet J. (2010) Influence of type d personality on the evolution over time of quality of life, anxiety and depression. European Heart Journal 31:232. Notes: Title/abstract: Excluded. Wrong indication

Miller G, Randolph S, Forkner E, Smith B, and Galbreath AD. (2009) Long-term cost-effectiveness of disease management in systolic heart failure. Medical Decision Making 29:325-333. Notes: Title/abstract: Included. Full text: Included.

Miller G, Cohen JT, and Roehrig C. (2012) Cost-effectiveness of cardiovascular disease spending. Journal of the American College of Cardiology 60:2123-2124. Notes: Title/abstract: Excluded. Wrong study type.

Miller LW, Guglin M, and Rogers J. (2013) Cost of ventricular assist devices can we afford the progress? Circulation 127:743-748. Notes: Title/abstract: Excluded. Wrong study type.

Minshall M, Swan T, Slusarek B, and Ikramuddin S. (2009) Cost-effectiveness of the Roux-en-Y gastric bypass surgery compared with medical management for treatment of Type 2 Diabetes Mellitus (T2DM) in Spain, Italy, and Sweden. Obesity Surgery 19:1003-1004. Notes: Title/abstract: Excluded. Wrong indication

Minshall M, Swan T, Slusarek B, and Ikramuddin S. (2009) Cost-effectiveness of the Roux-en-Y gastric bypass surgery compared with medical management for treatment of Type 2 Diabetes Mellitus (T2DM) in The UK, France, and Germany. Obesity Surgery 19:1003. Notes: Duplicate

Mitropoulos M and Elefteriades Md JA. (2001) Myocardial revascularization as a therapeutic strategy in the patient with advanced ventricular dysfunction. Heart Failure Reviews 6:163-175. Notes: Title/abstract: Excluded. Wrong study type.

Modi GK. (2011) Masala. National Medical Journal of India 24:59. Notes: Title/abstract: Excluded. Wrong study type.

Moertl D, Steiner S, Coyle D, and Berger R. (2013) Cost-utility analysis of nt-probnp-guided multidisciplinary care in chronic heart failure. International Journal of Technology Assessment in Health Care 29:3-11. Notes: Title/abstract: Included. Full text: Included.

Mohiuddin SM and Hilleman DE. (1991) Substituting nifedipine-GITS for immediate-release calcium-channel antagonists in patients with stable angina pectoris. Current Therapeutic Research - Clinical and Experimental 50:546-552. Notes: Title/abstract: Excluded. Wrong study type.

Moravec CS. (2008) Biofeedback therapy in cardiovascular disease: rationale and research overview. Cleveland Clinic journal of medicine 75 Suppl 2:S35-S38. Notes: Title/abstract: Excluded. Wrong study type.

Morcillo Serra C, Aguado O, Delas J, and Rosell F. (2007) Utility of the Minnesota living with heart failure questionnaire for assessing quality of life in heart failure patients. Revista Espanola de Cardiologia 60:1093-1096. Notes: Title/abstract: Excluded. Wrong study type.

Moreno SG, Novielli N, and Cooper NJ. (2012) Cost-effectiveness of the implantable HeartMate II left ventricular assist device for patients awaiting heart transplantation. Journal of Heart and Lung Transplantation 31:450-458. Notes: Title/abstract: Excluded. Wrong indication

Morgan JM, Gill J, Ng A, McComb J, Roderick P, Seed A, Williams S, Witte K, Wright D, and Cowie M. (2012) Economic analysis of a feasibility study of remote monitoring in heart failure (REM-HF-F). Europace 14:iv16. Notes: Title/abstract: Excluded. Wrong study type.

Morgan K, McGee H, and Shelley E. (2007) Quality of life assessment in heart failure interventions: A 10-year (1996-2005) review. European Journal of Cardiovascular Prevention and Rehabilitation 14:589-607. Notes: Title/abstract: Excluded. Wrong study type.

Morimoto T, Hayashino Y, Shimbo T, Izumi T, and Fukui T. (2004) Is B-type natriuretic peptide-guided heart failure management cost-effective? International Journal of Cardiology 96:177-181. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. Refers to Havranek 1999

Moskowitz AJ, Weinberg AD, Oz MC, and Williams DL. (1997) Quality of life with an implanted left ventricular assist device. Annals of Thoracic Surgery 64:1764-1769. Notes: Title/abstract: Excluded. Wrong indication

Mostafa T. (2008) Oral phosphodiesterase type 5 inhibitors: Nonerectogenic beneficial uses. Journal of Sexual Medicine 5:2502-2518. Notes: Title/abstract: Excluded. Wrong study type.

Motheral B. (2011) In reply. American Journal of Managed Care 17:e90. Notes: Title/abstract: Excluded. Wrong study type.

Moulaert VR, Verbunt JA, van Heugten CM, Bakx WG, Gorgels AP, Bekkers SC, de Krom MC, and Wade DT. (2007) Activity and Life After Survival of a Cardiac Arrest (ALASCA) and the effectiveness of

an early intervention service: design of a randomised controlled trial. BMC Cardiovascular Disorders 7:26. Notes: Title/abstract: Excluded. Wrong study type.

Moulaert VRMP, Verbunt JA, van Heugten CM, Bakx WGM, Gorgels APM, Bekkers SCAM, de Krom MCFT, and Wade DT. (2007) Activity and life after survival of a cardiac arrest (ALASCA) and the effectiveness of an early intervention service: Design of a randomised controlled trial. BMC Cardiovascular Disorders 7. Notes: Duplicate

Moutzouri E, Tsimihodimos V, Rizos E, and Elisaf M. (2011) Prediabetes: To treat or not to treat? European Journal of Pharmacology 672:9-19. Notes: Title/abstract: Excluded. Wrong study type.

Movsowitz C and Mittal S. (2011) Remote patient management using implantable devices. Journal of Interventional Cardiac Electrophysiology 31:81-90. Notes: Title/abstract: Excluded. Wrong study type.

Mudge AM, Denaro CP, Scott AC, Atherton JJ, Meyers DE, Marwick TH, Adsett JA, Mullins RW, Suna JM, Scuffham PA, and Orourke PK. (2011) Exercise training in recently hospitalized heart failure patients enrolled in a disease management programme: Design of the EJECTION-HF randomized controlled trial. European Journal of Heart Failure 13:1370-1375. Notes: Title/abstract: Excluded. Wrong study type Title/abstract: Excluded. Wrong study type.

Mueller C. (2008) Cost-effectiveness of B-type natriuretic peptide testing. Congestive heart failure (Greenwich, Conn.) 14:35-37. Notes: Title/abstract: Excluded. Wrong study type Title/abstract: Excluded. Wrong study type.

Munoz R, Martinez-Ferrer J, Delgado J, Rodriguez Barrios JM, Caro JJ, and Guo S. (2010) Can adding cardiac resynchronization compensate to optimized pharmacological treatment in patients with heart failure in Spain? Pharmacoeconomics - Spanish Research Articles 7:13-25. Notes: Title/abstract: Excluded. Not in English

Myers R and Michaud G. (2013) Tunneled Pleural Catheters: An Update for 2013. Clinics in Chest Medicine 34:73-80. Notes: Title/abstract: Excluded. Wrong study type.

Nanda U and Andresen EM. (1998) Health-related quality of life: A guide for the health professional. Evaluation and the Health Professions 21:179-215. Notes: Title/abstract: Excluded. Wrong study type.

Nanevicz T, Piette J, Zipkin D, Serlin M, Ennis S, De Marco T, and Modin G. (2000) The feasibility of a telecommunications service in support of outpatient congestive heart failure care in a diverse patient population. Congestive Heart Failure 6:140-145. Notes: Title/abstract: Excluded. Wrong study type.

Neumann PJ and Cohen JT. (2008) Reducing cardiovascular disease. Diabetes Care 31:1708-1709. Notes: Title/abstract: Excluded. Wrong study type.

Neyt M, Stroobandt S, Obyn C, Camberlin C, Devriese S, De Laet C, and Van Brabandt H. (2011) Cost-effectiveness of cardiac resynchronisation therapy for patients with moderate-to-severe heart failure. Value in Health 14:A253. Notes: Title/abstract: Excluded. Conference abstract

Nherera L, Calvert NW, Demott K, Humphries SE, Neil HAW, Minhas R, and Thorogood M. (2010) Cost-effectiveness analysis of the use of a high-intensity statin compared to a low-intensity statin in the management of patients with familial hypercholesterolaemia. Current Medical Research and Opinion 26:529-536. Notes: Title/abstract: Excluded. Wrong indication

Nichol G, Laupacis A, Stiell IG, O'Rourke K, Anis A, Bolley H, and Detsky AS. (1996) Cost-effectiveness analysis of potential improvements to emergency medical services for victims of out-of-hospital cardiac arrest. Annals of Emergency Medicine 27:711-720. Notes: Title/abstract: Excluded. Wrong indication

Nichol G, Hallstrom AP, Ornato JP, Riegel B, Stiell LG, Valenzuela T, Wells GA, White RD, and Weisfeldt ML. (1998) Potential cost-effectiveness of public access defibrillation in the United States. Circulation 97:1315-1320. Notes: Title/abstract: Excluded. Wrong indication

Nichol G, Stiell IG, Hebert P, Wells GA, Vandemheen K, and Laupacis A. (1999) What is the quality of life for survivors of cardiac arrest? A prospective study. Academic Emergency Medicine 6:95-102. Notes: Title/abstract: Included. Full text: Excluded. Wrong health states/indication.

Nichol G, Valenzuela T, Roe D, Clark L, Huszti E, and Wells GA. (2003) Cost effectiveness of defibrillation by targeted responders in public settings. Circulation 108:697-703. Notes: Title/abstract: Excluded. Wrong indication

Nichol G, Kaul P, Huszti E, and Bridges JFP. (2004) Cost-effectiveness of cardiac resynchronization therapy in patients with symptomatic heart failure. Annals of Internal Medicine 141:343-29. Notes: Title/abstract: Included. Full text: Included

Nichol G, Huszti E, Birnbaum A, Mahoney B, Weisfeldt M, Travers A, Christenson J, and Kuntz K. (2009) Cost-Effectiveness of Lay Responder Defibrillation for Out-of-Hospital Cardiac Arrest. Annals of Emergency Medicine 54:226-235. Notes: Title/abstract: Excluded. Wrong indication

Nilsson J, Anullkerborg O, Lindgren P, and Bascle S. (2010) Canadian cost-effectiveness analysis of dronedarone versus other anti-arrhytmic drugs in patients with paroxysmal and persistent atrial fibrillation. Value in Health 13:A355. Notes: Title/abstract: Excluded. Wrong study type.

Nolte JEH, Neumann T, Neumann A, Manne J, Mostardt S, Abbara S, Brady TJ, Hoffmann U, Gazelle GS, Wasem J, and Goehler A. (2011) Cardiovascular disease screening in hiv-infected patients - A cost-effectiveness analysis. Value in Health 14:A8. Notes: Title/abstract: Excluded. Wrong study type.

Norum J, Olsen JA, Wist EA, and Lonning PE. (2007) Trastuzumab in adjuvant breast cancer therapy. A model based cost-effectiveness analysis. Acta Oncologica 46:153-164. Notes: Title/abstract: Excluded. Wrong study type.

Noyes K, Corona E, Veazie P, Dick AW, Zhao H, and Moss AJ. (2009) Examination of the effect of implantable cardioverter-defibrillators on health-related quality of life: Based on results from the multicenter automatic defibrillator trial-ii. American Journal of Cardiovascular Drugs 9:393-400. Notes: Title/abstract: Included. Full text: Included. HUI3

Nunes AJ, Wiebe N, Chatterley P, MacArthur RG, and Klarenbach SW. (2012) Systematic review of the cost-effectiveness of mechanical circulatory support. Canadian Journal of Cardiology 28:S176-S177. Notes: Title/abstract: Excluded. Wrong study type

Nurmohamed MT and Dijkmans BAC. (2005) Efficacy, tolerability and cost effectiveness of disease-modifying antirheumatic drugs and biologic agents in rheumatoid arthritis. Drugs 65:661-694. Notes: Title/abstract: Excluded. Wrong indication

O'Donnell CP and Landzberg MJ. (2002) The 'failing' Fontan circulation. Progress in Pediatric Cardiology 16:105-114. Notes: Title/abstract: Excluded. Wrong study type.

O'Donoghue M and Sabatine MS. (2006) Appropriate invasive and conservative treatment approaches for patients with ST-elevation MI. Current Treatment Options in Cardiovascular Medicine 8:3-11. Notes: Title/abstract: Excluded. Wrong study type.

O'Hagan A and Stevens JW. (2002) Bayesian methods for design and analysis of cost-effectiveness trials in the evaluation of health care technologies. Statistical Methods in Medical Research 11:469-490. Notes: Title/abstract: Excluded. Wrong study type.

O'Reilly D, Blackhouse G, El-Hadi W, and Goeree R. (2010) Using the Cardiff Long Term Model to estimate the long-term cost-utility of adding Onglyza(trademark) (saxagliptin) versus a thiazolidinedione (TZD) in patients with type 2 diabetes mellitus (T2DM) with insufficient glycemic

control using maximal doses of metformin monotherapy and after failure or contraindication to sulfonylurea combination therapy. Journal of Population Therapeutics and Clinical Pharmacology 17:e109. Notes: Title/abstract: Excluded. Wrong indication

O'Reilly D, Holbrook A, Blackhouse G, Troyan S, and Goeree R. (2012) Cost-effectiveness of a shared computerized decision support system for diabetes linked to electronic medical records. Journal of the American Medical Informatics Association 19:341-345. Notes: Title/abstract: Excluded. Wrong study type.

Oba Y. (2009) Cost-effectiveness of long-term oxygen therapy for chronic obstructive pulmonary disease. American Journal of Managed Care 15:97-104. Notes: Title/abstract: Excluded. Wrong indication

Occhetta E, Cavallino C, Baduena L, Plebani L, and Marino P. (2011) Cardiologic ambulatory for chronic heart failure: Fashion or real utility? Mediterranean Journal of Pacing and Electrophysiology 13:20-23. Notes: Title/abstract: Excluded. Wrong study type.

Ogawa T, Tanabe S, Koike S, and Imamura T. (2012) Cost-effectiveness analysis of public-access automated external defibrillators in Japan. Circulation 126. Notes: Title/abstract: Excluded. Wrong indication

Olin RL, Kanetsky PA, Ten Have TR, Nasta SD, Schuster SJ, and Andreadis C. (2010) Determinants of the optimal first-line therapy for follicular lymphoma: A decision analysis. American Journal of Hematology 85:255-260. Notes: Title/abstract: Excluded. Wrong study type.

Oshinowo J. (2004) Maximizing quality of life and optimizing health care utilization by older adults with congestive heart faliure. Geriatrics and Aging 7:33-37. Notes: Title/abstract: Excluded. Wrong study type.

Ozasa N, Morimoto T, Furukawa Y, Shizuta S, Nishiyama K, Kita T, and Kimura T. (2008) Effects of ICD implantation on quality-adjusted life years in patients with congestive heart failure. International Journal of Cardiology 123:213-216. Notes: Title/abstract: Included. Full text: Included.

Pandor A, Eggington S, Paisley S, Tappenden P, and Sutcliffe P. (2006) The clinical and cost-effectiveness of oxaliplatin and capecitabine for the adjuvant treatment of colon cancer: Systematic review and economic evaluation. Health Technology Assessment 10:iii-89. Notes: Title/abstract: Excluded. Wrong indication.

Paniagua D, Lopez-Jimenez F, Londono JC, Mangione CM, Fleischmann K, and Lamas GA. (2002) Outcome and cost-effectiveness of cardiopulmonary resuscitation after in-hospital cardiac arrest in octogenarians. Cardiology 97:6-11. Notes: Title/abstract: Excluded. Wrong study type.

Papadakis S, Oldridge NB, Coyle D, Mayhew A, Reid RD, Beaton L, Dafoe WA, and Angus D. (2005) Economic evaluation of cardiac rehabilitation: A systematic review. European Journal of Cardiovascular Prevention and Rehabilitation 12:513-520. Notes: Title/abstract: Excluded. Wrong indication

Patani N and Mokbel K. (2010) Herceptin and breast cancer: An overview for surgeons. Surgical Oncology 19:e11-e21. Notes: Title/abstract: Excluded. Wrong study type.

Patel H, Shafazand M, Ekman I, Hojgard S, Swedberg K, and Schaufelberger M. (2008) Home care as an option in worsening chronic heart failure- A pilot study to evaluate feasibility, quality adjusted life years and cost-effectiveness. European Journal of Heart Failure 10:675-681. Notes: Title/abstract: Included. Full text: Included.

Patel PC, Stewart GC, Kittleson MM, Cowger JA, Patel CB, Mountis MM, Johnson FL, Rame JE, Testani J, Guglin ME, Teuteberg JJ, and Drazner MH. (2012) Patients with intermacs 4-7 heart failure have reduced quality of life. Journal of Heart and Lung Transplantation 31:S62-S63. Notes: Title/abstract: Excluded. Wrong indication.

Paz SH, Liu H, Fongwa MN, Morales LS, and Hays RD. (2009) Readability estimates for commonly used health-related quality of life surveys. Quality of Life Research 18:889-900. Notes: Title/abstract: Excluded. Wrong study type.

Pearson M. (2005) Lessons from the management of acute myocardial infarction. Heart 91:ii28-ii30. Notes: Title/abstract: Excluded. Wrong study type.

Pell JP, Walker A, and Cobbe SM. (2007) Cost-effectiveness of automated external defibrillators in public places: Con. Current Opinion in Cardiology 22:5-10. Notes: Title/abstract: Excluded. Wrong study type Title/abstract: Excluded. Wrong study type.

Pepke-Zaba J, Beardsworth A, Chan M, and Angalakuditi M. (2009) Effects of tadalafil on health-related quality of life in patients with pulmonary arterial hypertension. Value in Health 12:A504. Notes: Title/abstract: Excluded. Wrong study type.

Perez A, Touchette DR, DiDomenico RJ, Stamos TD, and Walton SM. (2011) Comparison of rate control versus rhythm control for management of atrial fibrillation in patients with coexisting heart failure: A cost-effectiveness analysis. Pharmacotherapy 31:552-565. Notes: Title/abstract: Excluded. Wrong indication

Perry CM. (2011) Liraglutide: A review of its use in the management of type 2 diabetes mellitus. Drugs 71:2347-2373. Notes: Title/abstract: Excluded. Wrong study type.

Pickard AS, Tawk R, and Shaw JW. (2012) The effect of chronic conditions on stated preferences for health. European Journal of Health Economics1-6. Notes: Title/abstract: Excluded. Wrong indication.

Pietzsch JB, Geisler BP, and Akehurst RL. (2012) Long-term clinical effectiveness and cost-effectiveness of catheter-based renal denervation in the UK. A model-based projection based on the symplicity HTN-2 trial. Value in Health 15:A349. Notes: Title/abstract: Excluded. Wrong study type.

Pietzsch JB, Geisler B, and Esler M. (2012) Efficacy and clinical and economic effectiveness in resistant hypertensive subgroups. Journal of the American College of Cardiology 59:E1716. Notes: Title/abstract: Excluded. Wrong indication.

Pihl E, Cider A, Stromberg A, Fridlund B, and Martensson J. (2011) Exercise in elderly patients with chronic heart failure in primary care: Effects on physical capacity and health-related quality of life. European Journal of Cardiovascular Nursing 10:150-158. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Pihl EP, Cider A, Stromberg A, Fridlund B, and Martensson J. (2011) Exercise in elderly patients with chronic heart failure in primary care; Effects on physical capacity and health-related quality of life. European Journal of Cardiovascular Nursing 10:S25. Notes: Duplicate

Pinto EB, Maso I, Pereira JLB, Fukuda TG, Seixas JC, Menezes DF, Cincura C, Neville IS, Jesus PAP, and Oliveira-Filho J. (2011) Differential aspects of stroke and congestive heart failure in quality of life reduction: A case series with three comparison groups. Health and Quality of Life Outcomes 9. Notes: Title/abstract: Excluded. Wrong indication.

Pinto EB, Maso I, Pereira JL, Fukuda TG, Seixas JC, Menezes DF, Cincura C, Neville IS, Jesus PA, and Oliveira-Filho J. (2011) Differential aspects of stroke and congestive heart failure in quality of life reduction: a case series with three comparison groups. Health and Quality of Life Outcomes 9:65. Notes: Duplicate

Piotrowicz E and Piotrowicz R. (2011) Telemonitoring in heart failure rehabilitation. European Cardiology 7:66-69. Notes: Title/abstract: Excluded. Wrong study type

Plesnila-Frank C, Asukai Y, Ehlken B, Giannitsis E, Rieber J, Berger K, Mardekian J, and Rublee DA. (2009) A life-long cost-effectiveness markov model comparing high-dose versus standard dose statin

therapy in acute coronary syndrome patients. Value in Health 12:A146-A147. Notes: Title/abstract: Excluded. Wrong study type.

Pletcher MJ and Pignone M. (2011) Evaluating the clinical utility of a biomarker: A review of methods for estimating health impact. Circulation 123:1116-1124. Notes: Title/abstract: Excluded. Wrong study type

Plosker GL and Keam SJ. (2006) Candesartan cilexetil: A pharmacoeconomic review of its use in chronic heart failure and hypertension. PharmacoEconomics 24:1249-1272. Notes: Title/abstract: Excluded. Wrong indication.

Plosker GL and Keam SJ. (2007) Spotlight on the pharmacoeconomics of candesartan cilexetil in chronic heart failure and hypertension. Disease Management and Health Outcomes 15:57-63. Notes: Title/abstract: Excluded. Wrong study type.

Plosker GL. (2011) Interferon-(beta)-1b: A review of its use in multiple sclerosis. CNS Drugs 25:67-88. Notes: Title/abstract: Excluded. Wrong study type

Pogach LM and Aron DC. (2009) A proposal for a new measure to assess efficiency of diabetes care. Journal of Clinical Outcomes Management 16:263-270. Notes: Title/abstract: Excluded. Wrong study type.

Poggio R, Augustovsky F, Caporale J, Irazola V, and Santiago M. (2012) Cost-effectiveness of cardiac resynchronization therapy: Perspective from Argentina. International Journal of Technology Assessment in Health Care 28:429-435. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Linde 2011

Ponzone R and Sismondi P. (2005) Selected highlights from the 27th San Antonio Breast Cancer Symposium. Expert Opinion on Pharmacotherapy 6:1257-1267. Notes: Title/abstract: Excluded. Wrong study type.

Postmus D, Abdul Pari AA, Jaarsma T, Luttik ML, Van Veldhuisen DJ, Hillege HL, and Buskens E. (2011) A trial-based economic evaluation of 2 nurse-led disease management programs in heart failure. American Heart Journal 162:1096-1104. Notes: Title/abstract: Excluded. Wrong study type.

Pradelli L, Iannazzo S, and Zaniolo O. (2009) The cost effectiveness and cost utility of valsartan in chronic heart failure therapy in ITALY: A probabilistic markov model. American Journal of Cardiovascular Drugs 9:383-392. Notes: Title/abstract: Included. Full text: Included.

Pressler SJ, Eckert GJ, Morrison GC, Murray MD, and Oldridge NB. (2011) Evaluation of the Health Utilities Index Mark-3 in heart failure. Journal of Cardiac Failure 17:143-150. Notes: Title/abstract: Included. Full text: Included

Priori SG, Bossaert LL, Chamberlain DA, Napolitano C, Arntz HR, Koster RW, Monsieurs KG, Capucci A, and Wellens HJ. (2004) ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. European Heart Journal 25:437-445. Notes: Title/abstract: Excluded. Wrong study type.

Probstfield JL. (2003) How cost-effective are new preventive strategies for cardiovascular disease? American Journal of Cardiology 91:22G-27G. Notes: Title/abstract: Excluded. Wrong study type Title/abstract: Excluded. Wrong study type.

Prochnicka A, Olszowska A, Baczynski D, Zelichowski G, and Wankowicz Z. (2009) Peritoneal dialysis as a therapeutic approach in congestive heart failure resistant to pharmacological treatment. Polskie Archiwum Medycyny Wewnetrznej 119:815-819. Notes: Title/abstract: Excluded. Wrong study type

Quesada A, Ricci R, Rodriguez-Barrio JM, Wolpert C, Navarro X, Arribas F, Adragao P, Almendral J, Muto C, De Las Heras A, Steinbeck G, and Santini M. (2010) Cost effectiveness of dual chamber ICDs.

An economic analysis from the DATAS trial. Europace 12:i93. Notes: Title/abstract: Excluded. Wrong study type

Quesada A, Almenar L, Diaz Molina B, Crespo C, Marti B, Mealing S, Linde C, and Daubert C. (2011) Cost-effectiveness analysis of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure based on the European cohort of the reverse study from the Spanish health system perspective. Value in Health 14:A249. Notes: Title/abstract: Excluded. Wrong study type.

Raina K, Callaway C, Rittenberger J, and Holm M. (2008) Neurological and functional status following cardiac arrest: Method and tool utility. Resuscitation 79:249-256. Notes: Title/abstract: Excluded. Wrong study type.

Raisch DW, Holdsworth MT, Marshik PL, and Campbell HM. (2004) Pharmacoeconomic analysis of therapies for pediatric patients. Expert Review of Pharmacoeconomics and Outcomes Research 4:483-487. Notes: Title/abstract: Excluded. Wrong study type.

Ram CVS. (2009) Direct inhibition of renin: A physiological approach to treat hypertension and cardiovascular disease. Future Cardiology 5:453-465. Notes: Title/abstract: Excluded. Wrong study type.

Ramani GV and Park MH. (2010) Update on the clinical utility of sildenafil in the treatment of pulmonary arterial hypertension. Drug Design, Development and Therapy 4:61-70. Notes: Title/abstract: Excluded. Wrong study type.

Ramirez De Arellano A, Brosa M, Franch J, Mauricio D, Alvarez C, Sanchez-Zamorano M, and De Rivas B. (2010) Cost-effectiveness analysis of saxagliptin in the treatment of diabetes mellitus type 2 in Spain. Value in Health 13:A292. Notes: Title/abstract: Excluded. Wrong indication.

Rao V, Naka Y, Catanese KA, Flannery MA, and Oz MC. (2001) Economic costs associated with implantable left ventricular assist device therapy. Journal of Congestive Heart Failure and Circulatory Support 2:31-34. Notes: Title/abstract: Excluded. Wrong study type

Raskin J, Smith TR, Wong K, Pritchett YL, D'Souza DN, Iyengar S, and Wernicke JF. (2006) Duloxetine versus routine care in the long-term management of diabetic peripheral neuropathic pain. Journal of Palliative Medicine 9:29-40. Notes: Title/abstract: Excluded. Wrong indication.

Rasmussen TB, Zwisler AD, Sibilitz KL, Risom SS, Bundgaard H, Gluud C, Moons P, Winkel P, Thygesen LC, Hansen JL, Norekval TM, and Berg SK. (2012) A randomised clinical trial of comprehensive cardiac rehabilitation versus usual care for patients treated for infective endocarditis-the CopenHeart IE trial protocol. BMJ Open 2. Notes: Title/abstract: Excluded. Wrong study type.

Ratner RE and Sathasivam A. (2011) Treatment Recommendations for Prediabetes. Medical Clinics of North America 95:385-395. Notes: Title/abstract: Excluded. Wrong study type.

Reed SD, Kaul P, Hernandez AF, Li Y, Eapen ZJ, Schulman KA, Whellan DJ, Westerhout CM, Massie B, Howlett JG, Armstrong PW, Starling R, O'Connor CM, and Califf RM. (2011) Medical resource use, costs and quality of life are similar between patients with acute decompensated heart failure treated with nesiritide versus placebo. Circulation 124. Notes: Title/abstract: Excluded. Wrong indication.

Reeder CE, Gourley GA, Wurtzbacher JD, and Reed P. (2000) The impact of angiotensin-converting enzyme inhibitors on managed care: Economic, clinical, and humanistic outcomes. American Journal of Managed Care 6:S112-S131. Notes: Title/abstract: Excluded. Wrong study type.

Reilly CM, Meadows K, Dunbar S, Culler S, and Smith A. (2010) Thirst and QOL in persons with heart failure. Heart and Lung: Journal of Acute and Critical Care 39:353. Notes: Title/abstract: Excluded. Wrong indication.

Reynolds MR, Zimetbaum P, Josephson ME, Ellis E, Danilov T, and Cohen DJ. (2009) Cost-effectiveness of radiofrequency catheter ablation compared with antiarrhythmic drug therapy for

paroxysmal atrial fibrillation. Circulation: Arrhythmia and Electrophysiology 2:362-369. Notes: Title/abstract: Excluded. Wrong indication

Reynolds MR, Morais E, and Zimetbaum P. (2010) Impact of hospitalization on health-related quality of life in atrial fibrillation patients in Canada and the United States: Results from an observational registry. American Heart Journal 160:752-758. Notes: Title/abstract: Excluded. Wrong indication

Reynolds MR, Nilsson J, Akerborg O, Jhaveri M, and Lindgren P. (2011) Cost effectiveness of dronedarone and standard care compared with standard care alone: US results of the athena life-time model. Circulation 124. Notes: Title/abstract: Excluded. Wrong indication

Reynolds MR and Essebag V. (2012) Economic burden of atrial fibrillation: Implications for intervention. American Journal of Pharmacy Benefits 4:58-65. Notes: Title/abstract: Excluded. Wrong study type.

Reynolds MR, Nilsson J, Akerborg O, Jhaveri M, and Lindgren P. (2013) Cost-effectiveness of dronedarone and standard of care compared with standard of care alone: US results of an ATHENA lifetime model. ClinicoEconomics and Outcomes Research 5:19-28. Notes: Title/abstract: Excluded. Wrong indication.

Ribeiro RA, Stella SF, Camey SA, Zimerman LI, Pimentel M, Rohde LE, and Polanczyk CA. (2010) Cost-effectiveness of implantable cardioverter-defibrillators in Brazil: Primary prevention analysis in the public sector. Value in Health 13:160-168. Notes: Title/abstract: Included. Full text: Included

Ribeiro RA, Stella SF, Zimerman LI, Pimentel M, Rohde LE, and Polanczyk CA. (2010) Cost-effectiveness of implantable cardioverter defibrillators in Brazil in the public and private sectors. Arquivos Brasileiros de Cardiologia 95:577-586. Notes: Title/abstract: Excluded. Not in English.

Richards AM. (2009) What We May Expect from Biomarkers in Heart Failure. Heart Failure Clinics 5:463-470. Notes: Title/abstract: Excluded. Wrong study type.

Richenbacher WE, Naka Y, Raines EP, Frazier OH, Couper GS, Pagani FD, Damme L, VanMeter CH, Magovern J, Gupta L, Seemuth SC, Weinberg AD, and Long JW. (2003) Surgical management of patients in the REMATCH trial. Annals of Thoracic Surgery 75:S86-S92. Notes: Title/abstract: Excluded. Wrong study type.

Riegel B, Mosesso VN, Birnbaum A, Bosken L, Evans LM, Feeny D, Holohan J, Jones CD, Peberdy MA, and Powell J. (2006) Stress reactions and perceived difficulties of lay responders to a medical emergency. Resuscitation 70:98-106. Notes: Title/abstract: Excluded. Wrong study type.

Rivera DA and Bristow MR. (2005) Cardiac resynchronization - A heart failure perspective. Annals of Noninvasive Electrocardiology 10:16-23. Notes: Title/abstract: Excluded. Wrong study type.

Roalfe AK, Bryant TL, Davies MH, Hackett TG, Saba S, Fletcher K, Lip GYH, Hobbs FDR, and Mant J. (2012) A cross-sectional study of quality of life in an elderly population (75 years and over) with atrial fibrillation: Secondary analysis of data from the Birmingham Atrial Fibrillation Treatment of the Aged study. Europace 14:1420-1427. Notes: Title/abstract: Excluded. Wrong indication.

Roda J, Rodriguez Barrios JM, Caro I, Deniz HB, Xenakis JJ, Ward A, and Caro JJ. (2009) Modeling of the clinical benefit and economic impact of pacemakers implantation with managed ventricular pacing. Pharmacoeconomics - Spanish Research Articles 6:115-125. Notes: Title/abstract: Excluded. Wrong indication.

Rogers JG, Bostic RR, Tong KB, Adamson R, Russo M, and Slaughter MS. (2012) Cost-effectiveness analysis of continuous-flow left ventricular assist devices as destination therapy. Circulation: Heart Failure 5:10-16. Notes: Title/abstract: Excluded. Wrong indication

Rogers JG, Bostic RR, Tong KB, Adamson R, Russo M, and Slaughter MS. (2012) Response to letter regarding article, cost-effectiveness analysis of continuous flow left ventricular assist devices as

destination therapy. Circulation: Heart Failure 5:e51. Notes: Title/abstract: Excluded. Wrong study type.

Roine E, Roine RP, Rasanen P, Vuori I, Sintonen H, and Saarto T. (2009) Cost-effectiveness of interventions based on physical exercise in the treatment of various diseases: A systematic literature review. International Journal of Technology Assessment in Health Care 25:427-454. Notes: Title/abstract: Excluded. Wrong indication.

Roman A, Escribano P, Barbera J, Sanchez Roman J, and Munoz R. (2010) Quality of life in patients diagnosed with pulmonary arterial hypertension - SQUALY study. American Journal of Respiratory and Critical Care Medicine 181. Notes: Title/abstract: Excluded. Wrong indication.

Roos JB, Doshi SN, Konorza T, Palacios I, Schreiber T, Borisenko OV, and Henriques JPS. (2013) The cost-effectiveness of a new percutaneous ventricular assist device for high-risk PCI patients: Mid-stage evaluation from the European perspective. Journal of Medical Economics 16:381-390. Notes: Title/abstract: Excluded. Wrong indication

Rosen RC, Contrada RJ, Gorkin L, and Kostis JB. (1997) Determinants of perceived health in patients with left ventricular dysfunction: A structural modeling analysis. Psychosomatic Medicine 59:193-200. Notes: Title/abstract: Excluded. Wrong study type.

Rosen VM, Taylor DCA, Parekh H, Pandya A, Thompson D, Kuznik A, Waters DA, Drummond M, and Weinstein MC. (2010) Cost effectiveness of intensive lipid-lowering treatment for patients with congestive heart failure and coronary heart disease inthe US. PharmacoEconomics 28:47-60. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication.

Rothberg MB, Bellantonio S, and Rose DN. (2003) Management of Influenza in Adults Older than 65 Years of Age: Cost-Effectiveness of Rapid Testing and Antiviral Therapy. Annals of Internal Medicine 139:321-329+I27. Notes: Title/abstract: Excluded. Wrong indication

Rublee D, Rieber J, Giannitsis E, Berger K, Ehlken B, Asukai Y, Plesnila-Frank C, and Mardekian J. (2009) Lifetime incremental effectiveness and cost-effectiveness of high-dose statin therapy versus standard-dose statin therapy in German patients with recent myocardial infarction. European Heart Journal 30:855. Notes: Title/abstract: Excluded. Wrong indication.

Russell S. (2012) The authors reply. British Journal of Cardiology 19:e1. Notes: Title/abstract: Excluded. Wrong study type.

Russell SD, Day JD, Stolen KQ, Kraus SM, Christman S, and Martin DO. (2009) The prevalence and characteristics of chronotropic incompetence in a general heart failure population: Results from the PEGASUS CRT trial. Journal of Cardiac Failure 15:S15. Notes: Title/abstract: Excluded. Wrong study type.

Rychlik R and Rulhoff H. (2005) Socioeconomic relevance of selected treatment strategies in patients with chronic heart failure. Expert Review of Pharmacoeconomics and Outcomes Research 5:277-286. Notes: Title/abstract: Excluded. Wrong study type.

Saborido CM, Hockenhull J, Bagust A, Boland A, Dickson R, and Todd D. (2010) Systematic review and cost-effectiveness evaluation of 'pill-in-the-pocket' strategy for paroxysmal atrial fibrillation compared to episodic in-hospital treatment or continuous antiarrhythmic drug therapy. Health Technology Assessment 14:1-103. Notes: Title/abstract: Excluded. Wrong indication

Sadowski DC, Bernstein CN, Bitton A, Croitoru K, Fedorak RN, and Griffiths A. (2009) Canadian Association of Gastroenterology clinical practice guidelines: The use of Crohn's disease factor-alpha antagonist therapy in Crohn's disease. Canadian Journal of Gastroenterology 23:185-202. Notes: Title/abstract: Excluded. Wrong study type.

Safley DM, Kennedy KF, Stansby G, Flather M, Cohen DJ, and Spertus JA. (2011) Prevalence and predictors of persistent health status impairment in patients referred to a vascular clinic with

intermittent claudication. European Journal of Vascular and Endovascular Surgery 42:355-362. Notes: Title/abstract: Excluded. Wrong study type

Samyshkin Y, Guillermin AL, Best JH, Brunell SC, and Lloyd A. (2012) Long-term cost-utility analysis of exenatide once weekly versus insulin glargine for the treatment of type 2 diabetes patients in the US. Journal of Medical Economics 15:6-13. Notes: Title/abstract: Excluded. Wrong indication.

Sanchez JE, Ortega T, Rodriguez C, Diaz-Molina B, Martin M, Garcia-Cueto C, Vidau P, Gago E, and Ortega F. (2010) Efficacy of peritoneal ultrafiltration in the treatment of refractory congestive heart failure. Nephrology Dialysis Transplantation 25:605-610. Notes: Title/abstract: Excluded. Wrong study type

Sanchez JE, Rodriguez C, Ortega T, Diaz-Molina B, Martin M, Garcia-Cueto C, Vidau P, and Gago E. (2010) The role of peritoneal ultrafiltration in the treatment of refractory congestive heart failure. European Journal of Heart Failure, Supplement 9:S145. Notes: Title/abstract: Excluded. Wrong study type.

Sanchez RA, Ayala M, Baglivo H, Velazquez C, Burlando G, Kohlmann O, Jimenez J, Jaramillo PL, Brandao A, Valdes G, Alcocer L, Bendersky M, Ramirez AJ, and Zanchetti A. (2009) Latin American guidelines on hypertension. Journal of Hypertension 27:905-922. Notes: Title/abstract: Excluded. Wrong study type

Sanders GD, Kong MH, Al-Khatib SM, and Peterson ED. (2010) Cost-effectiveness of implantable cardioverter defibrillators in patients (greater-than or equal to)65 years of age. American Heart Journal 160:122-131. Notes: Title/abstract: Included. FUll text: Included.

Savage PD, Shaw AO, Van Buren P, Le Winter MM, Ades PA, and Toth MJ. (2010) Directly measured physical function in chronic heart failure: Favorable effects of high intensity resistance training. Journal of Cardiopulmonary Rehabilitation and Prevention 30:267-268. Notes: Title/abstract: Excluded. Wrong study type.

Sayers SL, Riegel B, Goldberg LR, Coyne JC, and Samaha FF. (2008) Clinical exacerbations as a surrogate end point in heart failure research. Heart and Lung: Journal of Acute and Critical Care 37:28-35. Notes: Title/abstract: Excluded. Wrong study type.

Schaefer M, DeLattre M, Gao X, Stephens J, Botteman M, and Morreale A. (2005) Assessing the cost-effectiveness of COX-2 specific inhibitors for arthritis in the Veterans Health Administration. Current Medical Research and Opinion 21:47-60. Notes: Title/abstract: Excluded. Wrong indication

Scheuringer M, Sahakyan N, Krobot KJ, and Ulrich V. (2012) Cost of clinical events in health economic evaluations in Germany: a systematic review. Cost Effectiveness and Resource Allocation 10. Notes: Title/abstract: Excluded. Wrong study type.

Schlosser K, White RJ, and Stewart DJ. (2012) Circulating microrna provide potential biomarkers of pulmonary arterial hypertension. Canadian Journal of Cardiology 28:S309. Notes: Title/abstract: Excluded. Wrong study type

Schneider KM, O'Donnell BE, and Dean D. (2009) Prevalence of multiple chronic conditions in the United States' Medicare population. Health and Quality of Life Outcomes 7:82. Notes: Title/abstract: Excluded. Wrong study type.

Schwarz B and Wild R. (2010) Cost-effectiveness analysis of ivabradine in chronic stable angina patients in an Austrian setting. Value in Health 13:A355-A356. Notes: Title/abstract: Excluded. Wrong study type.

Scott IA, Gray LC, Martin JH, and Mitchell CA. (2012) Minimizing inappropriate medications in older populations: A 10-step conceptual framework. American Journal of Medicine 125:529-537. Notes: Title/abstract: Excluded. Wrong study type.

Scott MG. (2010) When do new biomarkers make economic sense? Scandinavian Journal of Clinical and Laboratory Investigation 70:90-95. Notes: Title/abstract: Excluded. Wrong study type.

Scuffham PA and Tippett V. (2008) The cost-effectiveness of thrombolysis administered by paramedics. Current Medical Research and Opinion 24:2045-2058. Notes: Title/abstract: Excluded. Wrong indication.

Sculpher MJ, Pang FS, Manca A, Drummond MF, Golder S, Urdahl H, Davies LM, and Eastwood A. (2004) Generalisability in economic evaluation studies in healthcare: A review and case studies. Health Technology Assessment 8:iii-117. Notes: Title/abstract: Excluded. Wrong study type

Segal L, Day SE, Chapman AB, and Osborne RH. (2004) Can we reduce disease burden from osteoarthritis? An evidence-based priority-setting model. Medical Journal of Australia 180:S11-S17. Notes: Title/abstract: Excluded. Wrong study type.

Shah MR, O'Connor CM, Sopko G, Hasselblad V, Califf RM, and Stevenson LW. (2001) Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness (ESCAPE): Design and rationale. American Heart Journal 141:528-535. Notes: Title/abstract: Excluded. Wrong study type

Shah P, Rongione AJ, Hewitt PD, Rosner CM, May CW, Burton NA, and Desai SS. (2012) Is cardiac resynchronization therapy a cost-effective strategy in patients whose ultimate destination is a left ventricular assist device? Journal of Heart and Lung Transplantation 31:S50-S51. Notes: Title/abstract: Excluded. Wrong study type

Sharieff W and Kaulback K. (2007) Assessing automated external defibrillators in preventing deaths from sudden cardiac arrest: An economic evaluation. International Journal of Technology Assessment in Health Care 23:362-367. Notes: Title/abstract: Excluded. Wrong study type.

Sharples L, Buxton M, Caine N, Cafferty F, Demiris N, Dyer M, and Freeman C. (2006) Evaluation of the ventricular assist device programme in the UK. Health Technology Assessment 10:iii-108. Notes: Title/abstract: Excluded. Wrong indication

Sharples L, Buxton M, Caine N, Cafferty F, Demiris N, Dyer M, and Freeman C. (2006) Evaluation of the ventricular assist device programme in the UK. Health technology assessment (Winchester, England) 10:1-iv. Notes: Duplicate

Shaw L, Rodgers H, Price C, van Wijck F, Shackley P, Steen N, Barnes M, Ford G, and Graham L. (2010) BoTULS: A multicentre randomized controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. Health Technology Assessment 14:i-141. Notes: Title/abstract: Excluded. Wrong indication.

Sheldon R, Silver MT, and Singh D. (2006) Primary prevention using ICDs may be cost-effective for people with left ventricular systolic dysfunction. Evidence-based Cardiovascular Medicine 10:56-58. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type.

Shephard RJ, Kavanagh T, and Mertens DJ. (1998) On the prediction of physiological and psychological responses to aerobic training in patients with stable congestive heart failure. Journal of Cardiopulmonary Rehabilitation 18:45-51. Notes: Title/abstract: Excluded. Wrong study type.

Shepherd J, Rogers G, Anderson R, Main C, Thompson-Coon J, Hartwell D, Liu Z, Loveman E, Green C, Pitt M, Stein K, Harris P, Frampton GK, Smith M, Takeda A, Price A, Welch K, and Somerville M. (2008) Systematic review and economic analysis of the comparative effectiveness of different inhaled corticosteroids and their usage with long-acting beta2 agonists for the treatment of chronic asthma in adults and children aged 12 years and over. Health Technology Assessment 12:1-233. Notes: Title/abstract: Excluded. Wrong indication

Shimizu M, Crawford B, Ikewaki K, Taniguchi I, Kamae I, Dahlof B, Drost P, and Mochizuki S. (2009) Cost-effectiveness of valsartan in Japan: Results from the jikei heart study. Value in Health 12:A151. Notes: Title/abstract: Excluded. Wrong study type.

Shukla T, Nichol G, Wells G, Garrard L, Guo A, Davies R, Haddad H, Duchesne L, Freeman M, Gulenchyn K, Racine N, Humen D, Dekemp R, Chen L, Ruddy T, Chow B, Dasilva J, and Beanlands R. (2011) Does fluorodeoxyglucose positron emission tomography guided management improve quality of life in patients with left ventricular dysfunction? A quality of life substudy of the PARR2 trial. Journal of the American College of Cardiology 57:E799. Notes: Title/abstract: Excluded. Wrong indication.

Siddiqui MAA and Scott LJ. (2005) Infliximab: A review of its use in Crohn's disease and rheumatoid arthritis. Drugs 65:2179-2208. Notes: Title/abstract: Excluded. Wrong study type

Siebens K, Miljoen H, De Geest S, Drew B, Vrints C, and Denollet J. (2012) Type D (distressed) personality predicts impaired health status in patients presenting with chest pain suggestive of an acute coronary syndrome. European Heart Journal 33:179. Notes: Title/abstract: Excluded. Wrong indication

Slejko JF, Ghushchyan VH, and Sullivan PW. (2010) Comparison of health state utility estimates in cost-effectiveness analysis. Value in Health 13:A13. Notes: Title/abstract: Excluded. Wrong study type.

Smith-Palmer J, Curtis BH, Boye KS, Goodall G, and Pillemer SR. (2010) Anti-CD3 monoclonal antibody treatment in newly diagnosed Type 1 diabetes patients: A hypothetical modelling analysis. Diabetic Medicine 27:189-196. Notes: Title/abstract: Excluded. Wrong study type.

Smith B, Hughes-Cromwick PF, Forkner E, and Galbreath AD. (2008) Cost-effectiveness of telephonic disease management in heart failure. American Journal of Managed Care 14:106-115. Notes: Title/abstract: Included. Full text: Excluded. Insufficient detail.

Smith DG, Frech-Tamas F, Randle W, and Preblick R. (2007) Estimated cost savings associated with the use of valsartan in heart failure in a large US health plan. Journal of Medical Economics 10:229-238. Notes: Title/abstract: Excluded. Wrong study type

Smith P, May C, Santamaria N, Hendrie D, Sheehan M, Hung J, Chan K, Vickery A, Williamson J, and Thompson P. (2011) Randomised comparison of remote monitoring versus enhanced standard care for heart failure. Heart Lung and Circulation 20:S75. Notes: Title/abstract: Excluded. Wrong study type

Snyder A, Pae W, Boehmer J, Rosenberg G, Weiss W, Pierce W, Thompson J, Lewis J, Frank D, Zintak H, Scholl S, Korfer R, El-Banayosy A, Arusoglu L, Fey O, and Morshuis M. (2000) First clinical trials of a totally implantable destination therapy ventricular assist system. Journal of Congestive Heart Failure and Circulatory Support 1:185-192. Notes: Title/abstract: Excluded. Wrong study type.

Sorum PC, Muoz Sastre MT, Mullet E, and Gamelin A. (2001) Eliciting patient disutilities for the adverse outcomes of cardiopulmonary resuscitation. Resuscitation 48:265-273. Notes: Title/abstract: Excluded. Wrong indication

Spertus JA, Tooley J, Jones P, Poston C, Mahoney E, Deedwania P, Hurley S, Pitt B, and Weintraub WS. (2002) Expanding the outcomes in clinical trials of heart failure: The quality of life and economic components of EPHESUS (EPlerenone's neuroHormonal Efficacy and SUrvival Study). American Heart Journal 143:636-642. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type

Sra J. (2006) Cardiac activation and motion propagation: Next step in catheter navigation? Heart Rhythm 3:789-790. Notes: Title/abstract: Excluded. Wrong study type.

Stanek EJ, Oates MB, McGhan WF, Denofrio D, and Loh E. (2000) Preferences for treatment outcomes in patients with heart failure: Symptoms versus suvival. Journal of Cardiac Failure 6:225-232. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type

Starling RC, Naka Y, Boyle AJ, Stawinski G, John R, Jorde U, Russell SD, Conte JV, Aaronson KD, McGee EC, Cotts WG, Denofrio D, Pham DT, Farrar D, and Pagani FD. (2009) Initial FDA post-approval study INTERMACS registry results with a continuous flow left ventricular assist device as a bridge to heart transplantation. Journal of Cardiac Failure 15:S46. Notes: Title/abstract: Excluded. Wrong study type

Stecker EC. (2005) Can the nation afford ICDs for all patients with severe cardiomyopathy? ACC Current Journal Review 14:36-41. Notes: Title/abstract: Excluded. Wrong study type.

Stein K, Ratcliffe J, Round A, Milne R, and Brazier JE. (2006) Impact of discussion on preferences elicited in a group setting. Health and Quality of Life Outcomes 4. Notes: Title/abstract: Excluded. Wrong study type.

Stevens GA, King G, and Shibuya K. (2010) Deaths from heart failure: Using coarsened exact matching to correct cause-of-death statistics. Population Health Metrics 8. Notes: Title/abstract: Excluded. Wrong study type.

Stevenson LW. (2006) Implantable cardioverter-defibrillators for primary prevention of sudden death in heart failure: Are there enough bangs for the bucks? Circulation 114:101-103. Notes: Title/abstract: Excluded. Wrong study type.

Stevenson LW and Stevenson WG. (2006) Cost-effectiveness of ICDs. The New England journal of medicine 354:205-207. Notes: Title/abstract: Excluded. Wrong study type

Stevenson LW, Hellkamp AS, Leier CV, Sopko G, Koelling T, Warnica JW, Abraham WT, Kasper EK, Rogers JG, Califf RM, Schramm EE, and O'Connor CM. (2008) Changing Preferences for Survival After Hospitalization With Advanced Heart Failure. Journal of the American College of Cardiology 52:1702-1708. Notes: Title/abstract: Included. Full text: Excluded. Wrong study type (correlations)

Stevenson WG, Hernandez AF, Carson PE, Fang JC, Katz SD, Spertus JA, Sweitzer NK, Tang WHW, Albert NM, Butler J, Westlake Canary CA, Collins SP, Colvin-Adams M, Ezekowitz JA, Givertz MM, Hershberger RE, Rogers JG, Teerlink JR, Walsh MN, Stough WG, and Starling RC. (2012) Indications for cardiac resynchronization therapy: 2011 update from the Heart Failure Society of America guideline committee. Journal of Cardiac Failure 18:94-106. Notes: Title/abstract: Excluded. Wrong study type.

Stewart AGO and Hare D. (2009) Simple adjectives can measure patient autonomy, depression, anxiety, social support and social isolation. European Heart Journal 30:864. Notes: Title/abstract: Excluded. Wrong study type.

Stewart GC, Brooks K, Pratibhu PP, Tsang SW, Semigran MJ, Smith CM, Saniuk C, Camuso JM, Fang JC, Mudge GH, Couper GS, Baughman KL, and Stevenson LW. (2009) Thresholds of Physical Activity and Life Expectancy for Patients Considering Destination Ventricular Assist Devices. Journal of Heart and Lung Transplantation 28:863-869. Notes: Title/abstract: Excluded. Wrong study type.

Stewart S, Chan YK, Carrington MJ, and Scuffham P. (2012) Home-based management for chronic heart failure reduces recurrent hospital stay and total healthcare costs compared to a clinic-based program: Results from the WHICH? Trial. Circulation 126. Notes: Title/abstract: Excluded. Wrong indication

Stiell IG, Nichol G, Wells G, De Maio V, Nesbitt L, Blackburn J, and Spaite D. (2003) Health-Related Quality of Life Is Better for Cardiac Arrest Survivors Who Received Citizen Cardiopulmonary Resuscitation. Circulation 108:1939-1944. Notes: Title/abstract: Excluded. Wrong indication

Stiell IG, Nesbitt LP, Nichol G, Maloney J, Dreyer J, Beaudoin T, Blackburn J, and Wells GA. (2009) Comparison of the Cerebral Performance Category Score and the Health Utilities Index for Survivors

of Cardiac Arrest. Annals of Emergency Medicine 53:241-248. Notes: Title/abstract: Excluded. Wrong indication

Stollerman GH. (2001) In diastolic heart failure, an ACE in the hole? Hospital Practice 36:56. Notes: Title/abstract: Excluded. Wrong study type.

Stromberg A and Jaarsma T. (2008) Thoughts about death and perceived health status in elderly patients with heart failure. European Journal of Heart Failure 10:608-613. Notes: Title/abstract: Included. FUll text: Excluded. Wrong health states.

Stryer D and Lawrence W. (2002) Automated external defibrillators [5]. Annals of Internal Medicine 137:622. Notes: Title/abstract: Excluded. Wrong study type.

Subramaniam M, Abdin E, Vaingankar JA, Nan L, Heng D, McCrone P, and Chong SA. (2013) Impact of psychiatric disorders and chronic physical conditions on health-related quality of life: Singapore Mental Health Study. Journal of Affective Disorders 147:325-330. Notes: Title/abstract: Excluded. Wrong indication

Sukantarat KT, Manyande A, and Williamson RCN. (2000) Psychological symptoms mirror physical health during recovery from resection of a pancreatic neuroendocrine cancer. HPB 2:343-346. Notes: Title/abstract: Excluded. Wrong study type.

Sullivan MD, Levy WC, Russo JE, Crane B, and Spertus JA. (2007) Summary Health Status Measures in Advanced Heart Failure: Relationship to Clinical Variables and Outcome. Journal of Cardiac Failure 13:560-568. Notes: Title/abstract: Excluded. Wrong study type.

Sund B, Svensson L, Rosenqvist M, and Hollenberg J. (2012) Favourable cost-benefit in an early defibrillation programme using dual dispatch of ambulance and fire services in out-of-hospital cardiac arrest. European Journal of Health Economics 13:811-818. Notes: Title/abstract: Excluded. Wrong indication

Supino PG, Borer JS, Franciosa JA, Preibisz JJ, Hochreiter C, Isom OW, Krieger KH, Girardi LN, Bouraad D, and Forur L. (2009) Acceptability and Psychometric Properties of the Minnesota Living With Heart Failure Questionnaire Among Patients Undergoing Heart Valve Surgery: Validation and Comparison With SF-36. Journal of Cardiac Failure 15:267-277. Notes: Title/abstract: Excluded. Wrong study type.

Svedbom A, Pfister P, Miltenburger C, Holmstrom S, and BorgstrOm F. (2009) Potential health economic benefits of improving the cardiovascular safety profile of nsaids. Value in Health 12:A441-A442. Notes: Title/abstract: Excluded. Wrong study type.

Svedbom A and BorgstrOm F. (2010) Cost-effectiveness of NSAIDs in patients with existing heart disease and osteoarthritis. Osteoporosis International 21:S371. Notes: Title/abstract: Excluded. Wrong study type

Swetz KM, Stulak JM, Dunlay SM, and Gafford EF. (2012) Management of advanced heart failure in the elderly: Ethics, economics, and resource allocation in the technological era. Cardiology Research and Practice 1. Notes: Title/abstract: Excluded. Wrong study type

Szmurlo D, Schubert A, Kostrzewska K, Rys P, and Skrzekowska-Baran I. (2011) Economic analysis of the implementation of guidelines for type 2 diabetes control developed by Diabetes Poland: What increase in costs is justified by clinical results? Polskie Archiwum Medycyny Wewnetrznej 121:345-351. Notes: Title/abstract: Excluded. Wrong indication.

Szucs TD and Sokolovic E. (2000) Economic relevance of congestive heart failure. An overview of costs and cost-effectiveness of treatment. Herz 25:538-546. Notes: Title/abstract: Excluded. Wrong study type

Szucs TD, Holm MV, Schwenkglenks M, Zhang Z, Weintraub WS, Burnier M, and Erne P. (2006) Cost-effectiveness of eplerenone in patients with left ventricular dysfunction after myocardial infarction -

An analysis of the EPHESUS study from a swiss perspective. Cardiovascular Drugs and Therapy 20:193-204. Notes: Title/abstract: Excluded. Wrong indication

Tarride JE, Hopkins R, Blackhouse G, Bowen JM, Bischof M, Von Keyserlingk C, O'Reilly D, Xie F, and Goeree R. (2010) A review of methods used in long-term cost-effectiveness models of diabetes mellitus treatment. PharmacoEconomics 28:255-277. Notes: Title/abstract: Excluded. Wrong indication.

Tavazzi L. (2006) Of defibrillators and guidelines. Giornale italiano di cardiologia (2006) 7:228-233. Notes: Title/abstract: Excluded. Wrong study type.

Taylor M, Scuffham PA, Chaplin S, and Papo NL. (2009) An economic evaluation of valsartan for post-MI patients in the UK who are not suitable for treatment with ACE inhibitors. Value in Health 12:459-465. Notes: Title/abstract: Excluded. Wrong indication

Taylor RS and Elston J. (2009) The use of surrogate outcomes in model-based cost-effectiveness analyses: A survey of UK Health Technology Assessment reports. Health Technology Assessment 13:iii-40. Notes: Title/abstract: Excluded. Wrong study type.

Taylor SH. (1986) The role of transdermal nitroglycerin in the treatment of coronary heart disease. American Heart Journal 112:197-207. Notes: Title/abstract: Excluded. Wrong study type.

Thigpen JT. (2005) Innovations in anthracycline therapy: Overview. Community Oncology 2:3-7. Notes: Title/abstract: Excluded. Wrong study type.

Thomas D, Mathew M, Raghavan CV, Mohanta GP, and Reddy YP. (2012) Days lost due to disability of diclofenac-induced adverse drug reactions. Pharmacy Practice 10:40-44. Notes: Title/abstract: Excluded. Wrong study type.

Thomas DE, Yousef ZR, and Fraser AG. (2009) A critical comparison of echocardiographic measurements used for optimizing cardiac resynchronization therapy: Stroke distance is best. European Journal of Heart Failure 11:779-788. Notes: Title/abstract: Excluded. Wrong study type.

Thomas SP and Sanders P. (2012) Catheter Ablation for Atrial Fibrillation. Heart Lung and Circulation 21:395-401. Notes: Title/abstract: Excluded. Wrong study type.

Thompson Coon J, Hoyle M, Green C, Liu Z, Welch K, Moxham T, and Stein K. (2010) Bevacizumab, sorafenib tosylate, sunitinib and temsirolimus for renal cell carcinoma: A systematic review and economic evaluation. Health Technology Assessment 14:1-184. Notes: Title/abstract: Excluded. Wrong indication

Timlin L, Beaudet A, Wilson B, Bruhn D, Boye KS, Palmer JL, and Lloyd A. (2010) Long-term clinical outcomes of exenatide once-weekly versus insulin glargine for the treatment of type 2 diabetes projected using the core diabetes model. Value in Health 13:A284-A285. Notes: Title/abstract: Excluded. Wrong indication.

Toon PD. (2010) Do we spend too much time with Nellie the Elephant? British Journal of General Practice 60:55. Notes: Title/abstract: Excluded. Wrong study type.

Toren Y, Davrath LR, Abboud S, and Amit G. (2011) The cost-effectiveness of stress testing using high-frequency QRS analysis. Annals of Hematology 90:e18. Notes: Title/abstract: Excluded. Wrong indication.

Triedman JK and Alexander ME. (2010) Needle in a haystack: Modeling the incidence of sudden cardiac arrest in healthy children. Circulation 121:1283-1285. Notes: Title/abstract: Excluded. Wrong study type.

Tugwell P, Knottnerus JA, and Idzerda L. (2011) Editorial: Call for observational studies register. Journal of Clinical Epidemiology 64:457-458. Notes: Title/abstract: Excluded. Wrong study type

Tunis SL. (2011) Cost effectiveness of self-monitoring of blood glucose (SMBG) for patients with type 2 diabetes and not on insulin: Impact of modelling assumptions on recent Canadian findings. Applied Health Economics and Health Policy 9:351-365. Notes: Title/abstract: Excluded. Wrong indication.

Turner D, Wailoo A, Nicholson K, Cooper N, Sutton A, and Abrams K. (2003) Systematic review and economic decision modelling for the prevention and treatment of influenza A and B. Health Technology Assessment 7. Notes: Title/abstract: Excluded. Wrong indication

Turner DA, Paul S, Stone MA, Juarez-Garcia A, Squire I, and Khunti K. (2008) Cost-effectiveness of a disease management programme for secondary prevention of coronary heart disease and heart failure in primary care. Heart 94:1601-1606. Notes: Title/abstract: Included. Full text: Excluded. Wrong indicaiton.

Tusquets I, Garcia-Estevez L, Adrover E, Calvo L, Alvarez I, Garcia Mata J, Fernandez Y, Margueli M, Segui MA, Rodriguez C, Rodriguez Lescure A, Colomer R, Gascon P, Martin M, Alba E, Barnadas A, Llombart A, Albanell J, and Lluch A. (2010) Current controversies in the management of breast cancer. Clinical and Translational Oncology 12:278-286. Notes: Title/abstract: Excluded. Wrong study type.

Ulisney KL, Grady KL, Kirklin JK, Naftel DC, Gelijns AC, Moskowitz AJ, Young JB, Myers SL, and Wissman SA. (2009) Evaluating quality of life prior to MCSD implant is a challenge: Results from intermacs. Journal of Heart and Lung Transplantation 28:S269-S270. Notes: Title/abstract: Excluded. Wrong study type

Underwood M, Ashby D, Carnes D, Castelnuovo E, Cross P, Harding G, Hennessy E, Letley L, Martin J, Mt-Isa S, Parsons S, Spencer A, Vickers M, and Whyte K. (2008) Topical or oral ibuprofen for chronic knee pain in older people. The TOIB study. Health Technology Assessment 12:iii-155. Notes: Title/abstract: Excluded. Wrong study type.

Valentine WJ, Palmer AJ, Lammert M, Langer J, and Brandle M. (2011) Evaluating the long-term cost-effectiveness of liraglutide versus exenatide BID in patients with type 2 diabetes who fail to improve with oral antidiabetic agents. Clinical Therapeutics 33:1698-1712. Notes: Title/abstract: Excluded. Wrong indication.

Van Alem AP, Dijkgraaf MGW, Tijssen JGP, and Koster RW. (2004) Health system costs of out-of-hospital cardiac arrest in relation to time to shock. Circulation 110:1967-1973. Notes: Title/abstract: Excluded. Wrong study type.

Van Den Berg B. (2012) SF-6D population norms. Health Economics (United Kingdom) 21:1508-1512. Notes: Title/abstract: Excluded. Wrong study type.

van der Velde G, Hogg-Johnson S, Bayoumi AM, Cassidy JD, Cote P, Boyle E, Llewellyn-Thomas H, Chan S, Subrata P, Hoving JL, Hurwitz E, Bombardier C, and Krahn M. (2009) Identifying the Best Treatment Among Common Nonsurgical Neck Pain Treatments. A Decision Analysis. Journal of Manipulative and Physiological Therapeutics 32:S209-S218. Notes: Title/abstract: Excluded. Wrong study type.

van Eck JWM, Van Hemel NM, van den Bos A, Taks W, Grobbee DE, and Moons KGM. (2008) Predictors of improved quality of life 1 year after pacemaker implantation. American Heart Journal 156:491-497. Notes: Title/abstract: Excluded. Wrong indication.

Van Genugten MLL, Weintraub WS, Zhang Z, and Voors AA. (2005) Cost-effectiveness of eplerenone plus standard treatment compared with standard treatment in patients with myocardial infarction complicated by left ventricular systolic dysfunction and heart failure in the Netherlands. Netherlands Heart Journal 13:393-400. Notes: Title/abstract: Excluded. Wrong indication.

Van Hemel NM. (2007) A review of factors contributing to health related quality of life achieved with cardiac resynchronization therapy for heart failure. Minerva Cardioangiologica 55:783-802. Notes: Title/abstract: Excluded. Wrong study type.

Van Hout BA. (2009) The value of added life years as a function of age, prognosis and quality of life. Value in Health 12:A4-A5. Notes: Title/abstract: Excluded. Wrong study type.

Van Wijk S, Van Asselt T, Maeder MT, Muzzarelli S, Erne P, Estlinbaum W, Rickli H, Rickenbacher P, Pfisterer M, and Brunner-La Rocca HP. (2011) Cost-effectiveness of NT-proBNP-guided therapy in heart failure; results from the TIME-CHF study. European Heart Journal 32:161. Notes: Title/abstract: Excluded. Wrong study type.

Vanderlaan BF, Broder MS, Chang EY, Oratz R, and Bentley TGK. (2011) Cost-effectiveness of 21-gene assay in node-positive, early-stage breast cancer. American Journal of Managed Care 17:455-464. Notes: Title/abstract: Excluded. Wrong indication.

Vandvik PO, Lincoff AM, Gore JM, Gutterman DD, Sonnenberg FA, Alonso-Coello P, Akl EA, Lansberg MG, Guyatt GH, and Spencer FA. (2012) Primary and secondary prevention of cardiovascular disease: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of chest physicians evidence-based clinical practice guidelines. Chest 141:e637S-e668S. Notes: Title/abstract: Excluded. Wrong indication.

Vanston V and Stahl R. (2011) How's Charlie? Open heart surgery in the very old (341). Journal of Pain and Symptom Management 41:216. Notes: Title/abstract: Excluded. Wrong study type.

Vetter VL. (2009) The role of ECG screening in the evaluation of risk of sudden cardiac arrest in the young. PACE - Pacing and Clinical Electrophysiology 32:S6-S14. Notes: Title/abstract: Excluded. Wrong study type.

Vichairuangthum K, Yodla P, and Sakthong P. (2012) Cost-effectiveness of ivabradine in thai heart failure patient. Value in Health 15:A372. Notes: Title/abstract: Excluded. Wrong study type.

Vieira RD, Hueb W, Hlatky M, Favarato D, Rezende PC, Garzillo CL, Lima EG, Soares PR, Hueb AC, Pereira AC, Ramires JAF, and Filho RK. (2012) Cost-effectiveness analysis for surgical, angioplasty, or medical therapeutics for coronary artery disease: 5-year follow-up of medicine, angioplasty, or surgery study (MASS) II trial. Circulation 126:S145-S150. Notes: Title/abstract: Excluded. Wrong indication.

Vigna GB, Zuliani G, and Fellin R. (2011) Dyslipidemias in the older subject: Features, significance and treatment dilemmas. Clinical Lipidology 6:339-350. Notes: Title/abstract: Excluded. Wrong study type.

Volaklis KA and Tokmakidis SP. (2005) Resistance exercise training in patients with heart failure. Sports Medicine 35:1085-1103. Notes: Title/abstract: Excluded. Wrong study type.

Wagner M, Lindgren P, Merikle E, Goetghebeur M, and Jonsson B. (2009) Economic evaluation of high-dose (80 mg/day) atorvastatin treatment compared with standard-dose (20 mg/day to 40 mg/day) simvastatin treatment in Canada based on the Incremental Decrease in End-Points Through Aggressive Lipid-Lowering (IDEAL) trial. Canadian Journal of Cardiology 25:e362-e369. Notes: Title/abstract: Excluded. Wrong study type.

Walenta K, Sinning JM, Werner N, and Bohm M. (2011) Hotline update of clinical trials and registries presented at the American College of Cardiology Congress 2011. Clinical Research in Cardiology 100:475-482. Notes: Title/abstract: Excluded. Wrong study type.

Walker A, Sirel JM, Marsden AK, Cobbe SM, and Pell JP. (2003) Cost effectiveness and cost utility model of public place defibrillators in improving survival after prehospital cardiopulmonary arrest. British Medical Journal 327:1316-1319. Notes: Title/abstract: Excluded. Wrong indication

Walter E, Brennig C, and Schollbauer V. (2011) Cost effectiveness of adjuvant cyclophosphamide in the treatment of breast cancer in Spain. Value in Health 14:A455. Notes: Title/abstract: Excluded. Wrong indication.

Ward A, Guo S, and Caro JJ. (2006) Cost-Effectiveness of Cardiac Resynchronization Therapy. Journal of the American College of Cardiology 48:1283. Notes: Title/abstract: Excluded. Wrong study type.

Ward MA and Biddle AK. (2012) Cost-effectiveness analysis of dabigatran compared to warfarin for stroke prevention in atrial fibrillation in a medicare population. Value in Health 15:A121. Notes: Title/abstract: Excluded. Wrong study type.

Ward MJ, Eckman MH, Schauer DP, Raja AS, and Collins S. (2011) Cost-effectiveness of telemetry for hospitalized patients with low-risk chest pain. Academic Emergency Medicine 18:279-286. Notes: Title/abstract: Excluded. Wrong indication.

Warren SA and Nichol G. (2008) A call to arms to reduce premature deaths by using inexpensive resuscitation care. Critical Care 12. Notes: Title/abstract: Excluded. Wrong study type.

Warren SA and Nichol G. (2008) A call to arms to reduce premature deaths by using inexpensive resuscitation care. Critical care (London, England) 12:173. Notes: Duplicate

Watt M, Mealing S, Eaton J, Sculpher M, Brasseur P, Busca R, Moat N, Piazza N, and Palmer S. (2012) The authors' reply. Heart 98:1258. Notes: Title/abstract: Excluded. Wrong study type.

Waugh N, Cummins E, Royle P, Clar C, Marien M, Richter B, and Philip S. (2010) Newer agents for blood glucose control in type 2 diabetes: Systematic review and economic evaluation. Health Technology Assessment 14:3-247. Notes: Title/abstract: Excluded. Wrong indication

Wayne M, Tupper D, Aufderheide T, Mahoney B, Swor R, Domeier R, Olinger M, Holcomb R, Setum C, and Frascone R. (2012) Modified rankin score at hospital discharge is predictive of 1-year neurological function in survivors after cardiac arrest. Circulation 126. Notes: Title/abstract: Excluded. Wrong study type.

Weber KT, Andrews V, and Janicki JS. (1982) Cardiotonic agents in the management of chronic cardiac failure. American Heart Journal 103:639-649. Notes: Title/abstract: Excluded. Wrong study type.

Weintraub WS, Cole J, and Tooley JF. (2002) Cost and cost-effectiveness studies in heart failure research. American Heart Journal 143:565-576. Notes: Title/abstract: Excluded. Wrong study type.

Weintraub WS, Zhang Z, Mahoney EM, Kolm P, Spertus JA, Caro J, Ishak J, Goldberg R, Tooley J, Willke R, and Pitt B. (2005) Cost-effectiveness of eplerenone compared with placebo in patients with myocardial infarction complicated by left ventricular dysfunction and heart failure. Circulation 111:1106-1113. Notes: Title/abstract: Excluded. Wrong indication.

Weintraub WS. (2009) Controversies and opportunities in economic analysis of health care. Circulation: Cardiovascular Quality and Outcomes 2:402-403. Notes: Title/abstract: Excluded. Wrong study type.

Wells GA, Coyle D, Nichol G, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Heart Rhythm 9:S71. Notes: Title/abstract: Excluded. Wrong study type.

Wells GA, Coyle D, Coyle K, Talajic M, and Tang A. (2012) Cost effectiveness of cardiac resynchronization therapy (CRT) for mild to moderate heart failure. Canadian Journal of Cardiology 28:S419. Notes: Title/abstract: Excluded. Wrong study type.

Wexler DJ, Grant RW, Wittenberg E, Bosch JL, Cagliero E, Delahanty L, Blais MA, and Meigs JB. (2006) Correlates of health-related quality of life in type 2 diabetes. Diabetologia 49:1489-1497. Notes: Title/abstract: Excluded. Wrong indication

Wieser S, Ruthemann I, De Boni S, Eichler K, Pletscher M, Radovanovic D, and Auerbach H. (2011) Cost of acute coronary syndrome in Switzerland. Value in Health 14:A373. Notes: Title/abstract: Excluded. Wrong study type.

Wieser S, Ruthemann I, De Boni S, Eichler K, Pletscher M, Radovanovic D, Ulle T, and Auerbach H. (2012) Cost of acute coronary syndrome in Switzerland in 2008. Swiss Medical Weekly 142. Notes: Title/abstract: Excluded. Wrong indication.

Willan AR, Lin DY, Cook RJ, and Chen EB. (2002) Using inverse-weighting in cost-effectiveness analysis with censored data. Statistical Methods in Medical Research 11:539-551. Notes: Title/abstract: Excluded. Wrong study type.

Willan AR, Lin DY, and Manca A. (2005) Regression methods for cost-effectiveness analysis with censored data. Statistics in Medicine 24:131-145. Notes: Title/abstract: Excluded. Wrong study type.

Williams JA, Patel ND, Nwakanma LU, and Conte JV. (2006) Outcomes of surgical ventricular restoration following recent myocardial infarction. Journal of Cardiothoracic-Renal Research 1:51-58. Notes: Title/abstract: Excluded. Wrong study type.

Williams JA, Patel ND, Nwakanma LU, and Conte JV. (2007) Outcomes following surgical ventricular restoration in elderly patients with congestive heart failure. The American journal of geriatric cardiology 16:67-75. Notes: Title/abstract: Excluded. Wrong study type.

Wong D, Benson LN, Van Arsdell GS, Karamlou T, and McCrindle BW. (2008) Balloon angioplasty is preferred to surgery for aortic coarctation. Cardiology in the Young 18:79-88. Notes: Title/abstract: Excluded. Wrong study type.

Wong FL, Bhatia S, Kurian S, Landier W, Francisco L, Leisenring WM, Hudson MM, Armstrong GT, Mertens A, Stovall M, Robison LL, Lipshultz SE, and Armenian S. (2012) Efficacy of the Children's Oncology Group (COG) long-term follow-up (LTFU) guidelines in reducing risk of congestive heart failure (CHF) in childhood cancer survivors (CCS). Journal of Clinical Oncology 30. Notes: Title/abstract: Excluded. Wrong study type.

Woo J and Cockram C. (2000) Cost estimates for chronic diseases. Disease Management and Health Outcomes 8:29-41. Notes: Title/abstract: Excluded. Wrong study type.

Woodhouse RJ. (2009) Report from Great Britain. Pharmazeutische Industrie 71:1742-1746. Notes: Title/abstract: Excluded. Wrong study type.

Woolacott N, Vergel YB, Hawkins N, Kainth A, Khadjesari Z, Misso K, Light K, Asseburg C, Palmer S, Claxton K, Bruce I, Sculpher M, and Riemsma R. (2006) Etanercept and infliximab for the treatment of psoriatic arthritis: A systematic review and economic evaluation. Health Technology Assessment 10:iii-78. Notes: Title/abstract: Excluded. Wrong indication.

Wootton R, Gramotnev H, and Hailey D. (2009) A randomized controlled trial of telephone-supported care coordination in patients with congestive heart failure. Journal of Telemedicine and Telecare 15:182-186. Notes: Title/abstract: Excluded. Wrong indication.

Wu J, Wu JH, and Chang J. (2010) Long-term health outcomes of treatment with Liraglutide versus Glimepriride in type 2 diabetes patients in Asian setting. Value in Health 13:A526. Notes: Title/abstract: Excluded. Wrong study type.

Xu Z and Niu W. (2011) Evaluating the long-term cost-effectiveness of tight glycaemic control in patients with type 2 diabetes in China: A modeling study of long-term costs and health outcomes. Diabetes 60:A244. Notes: Title/abstract: Excluded. Wrong study type.

Yagudina R, Kulikov AU, and Arinina EE. (2010) Pharmacoeconomics modeling of long term results of type 2 diabetes mellitus treatment in patients using modern insulin analogues in contrast to oral

antidiabetic drugs or diet. Value in Health 13:A292. Notes: Title/abstract: Excluded. Wrong study type.

Yao G, Freemantle N, Calvert MJ, Bryan S, Daubert JC, and Cleland JGF. (2007) The long-term cost-effectiveness of cardiac resynchronization therapy with or without an implantable cardioverter-defibrillator. European Heart Journal 28:42-51. Notes: Title/abstract: Included. Full text: Included. EQ-5D

Yao G, Freemantle N, Flather M, Tharmanathan P, Coats A, and Poole-Wilson PA. (2008) Long-term cost-effectiveness analysis of nebivolol compared with standard care in elderly patients with heart failure: An individual patient-based simulation model. PharmacoEconomics 26:879-889. Notes: Title/abstract: Included. Full text: Excluded. Secondary publication. References Yao 2007.

Yi MS, Luckhaupt S, Mrus JM, and Tsevat J. (2004) Do medical house officers value the health of veterans differently from the health of non-veterans? Health and Quality of Life Outcomes 2. Notes: Title/abstract: Excluded. Wrong indication.

Yi Y, Philips Z, Bergman G, and Burslem K. (2010) Economic models in type 2 diabetes. Current Medical Research and Opinion 26:2105-2118. Notes: Title/abstract: Excluded. Wrong indication.

Young KC, Teeters JC, Benesch CG, Bisognano JD, and Illig KA. (2009) Cost-effectiveness of treating resistant hypertension with an implantable carotid body stimulator. Journal of Clinical Hypertension 11:555-563. Notes: Title/abstract: Excluded. Wrong indication.

Younis T and Skedgel C. (2008) Is trastuzumab a cost-effective treatment for breast cancer? Expert Review of Pharmacoeconomics and Outcomes Research 8:433-442. Notes: Title/abstract: Excluded. Wrong indication.

Younis T, Rayson D, and Skedgel C. (2011) The cost-utility of adjuvant chemotherapy using docetaxel and cyclophosphamide compared with doxorubicin and cyclophosphamide in breast cancer. Current Oncology 18:e288-e296. Notes: Title/abstract: Excluded. Wrong indication.

Zanaboni P, Marzegalli M, Landolina ME, Lunati M, Perego GB, Guenzati G, Curnis A, Borghetti F, Beccagutti G, Borghi G, and Masella C. (2012) Evaluation of telemonitoring for heart failure patients with implantable defibrillators: The evolvo (evolution of management strategies of heart failure patients with implantable defibrillators) study. Value in Health 15:A281. Notes: Title/abstract: Excluded. Wrong study type.

Zeliadt SB and Ramsey SD. (2010) Cost-effectiveness of prostate cancer chemoprevention among high-risk men. Expert Review of Pharmacoeconomics and Outcomes Research 10:505-508. Notes: Title/abstract: Excluded. Wrong indication.

Zhang P, Brown MB, Bilik D, Ackermann RT, Li R, and Herman WH. (2012) Health utility scores for people with type 2 diabetes in U.S. managed care health plans: Results from translating research into action for diabetes (TRIAD). Diabetes Care 35:2250-2256. Notes: Title/abstract: Excluded. Wrong indication.

Zhang Z, Mahoney EM, Kolm P, Spertus J, Caro J, Willke R, and Weintraub WS. (2010) Cost Effectiveness of Eplerenone in Patients with Heart Failure after Acute Myocardial Infarction Who were Taking Both ACE Inhibitors and (beta)-Blockers: Subanalysis of the EPHESUS. American Journal of Cardiovascular Drugs 10:55-63. Notes: Title/abstract: Excluded. Wrong indication.

Zhao L, Leung KF, Liu FB, Chen J, and Chan K. (2008) Responsiveness of the Chinese Quality of Life Instrument in patients with congestive heart failure. Chinese Journal of Integrative Medicine 14:173-179. Notes: Title/abstract: Excluded. Wrong study type.

Zimerman LI. (2008) Cardioverter-defibrillator in the primary prevention of sudden death: For all or for a few? Arquivos Brasileiros de Cardiologia 91:63-71. Notes: Title/abstract: Excluded. Wrong study type.

Zimetbaum PJ. (2007) A 59-year-old man considering implantation of a cardiac defibrillator. Journal of the American Medical Association 297:1909-1916. Notes: Title/abstract: Excluded. Wrong study type.

Zimovetz EA, Wilson K, Samuel M, and Beard SM. (2011) A review of cost-effectiveness of varenicline and comparison of cost-effectiveness of treatments for major smoking-related morbidities. Journal of Evaluation in Clinical Practice 17:288-297. Notes: Title/abstract: Excluded. Wrong indication.

(2000) Implantable cardioverter/defibrillator therapy: The meaning of terms. Canadian Journal of Cardiology 16:1325-1328. Notes: Title/abstract: Excluded. Wrong study type.

(2002) ASHP therapeutic position statement on the use of (beta)-blockers in survivors of acute myocardial infarction. American Journal of Health-System Pharmacy 59:2226-2232. Notes: Title/abstract: Excluded. Wrong study type.

(2004) Special report: cost-effectiveness of left-ventricular assist devices as destination therapy for end-stage heart failure. Technology Evaluation Center Assessment Program. Executive summary 19:1. Notes: Title/abstract: Excluded. Wrong study type.

(2004) Summaries for patients. The cost-effectiveness of cardiac resynchronization therapy for heart failure. Annals of Internal Medicine 141:I29. Notes: Title/abstract: Excluded. Wrong study type.

(2006) The management of hypertension in primary care: Updated guidance from NICE - Part 2. MeReC Bulletin 17:3-13. Notes: Title/abstract: Excluded. Wrong study type.

(2006) The management of hypertension in primary care: Updated guidance from NICE - Part 3. MeReC Bulletin 17:14-20. Notes: Title/abstract: Excluded. Wrong study type.

(2007) Disease management update. Disease Management and Health Outcomes 15:323-329. Notes: Title/abstract: Excluded. Wrong study type.

(2009) 2009 Annual Meeting Student Poster Abstract. Drug Information Journal 43. Notes: Title/abstract: Excluded. Wrong study type.

(2010) Vagus nerve stimulation for epilepsy. Drug and Therapeutics Bulletin 48:42-45. Notes: Title/abstract: Excluded. Wrong study type.

(2010) (black down triangle)Febuxostat for gout. Drug and Therapeutics Bulletin 48:78-82. Notes: Title/abstract: Excluded. Wrong study type.

(2010) Update on current care guidelines. Current care guideline: cardiac pacemaker therapy. Duodecim; lÃ¤Ã¤ketieteellinen aikakauskirja 126:391-392. Notes: Title/abstract: Excluded. Wrong study type.

(2010) Canadian Association of Cardiac Rehabilitation (Association Canadienne de Readaptation Cardiaque) 20th Annual Meeting and Scientific Abstracts. Journal of Cardiopulmonary Rehabilitation and Prevention 30. Notes: Title/abstract: Excluded. Wrong study type.

REFERENCES

1. Abraham WT, Young JB, Leon AR, Adler S, Bank AJ, Hall SA, Lieberman R, Liem LB, O'Connell JB, Schroeder JS, and Wheelan KR. (2004) Effects of cardiac resynchronization on disease progression in patients with left ventricular systolic dysfunction, an indication for an implantable cardioverter-defibrillator, and mildly symptomatic chronic heart failure. *Circulation* 110:2864-2868.

2. Adabag S, Roukoz H, Anand IS, and Moss AJ. (2011) Cardiac resynchronization therapy in patients with minimal heart failure: A systematic review and meta-analysis. *Journal of the American College of Cardiology* 58:935-941.

3. Al-Majed NS, McAlister FA, Bakal JA, and Ezekowitz JA. (2011) Meta-analysis: cardiac resynchronization therapy for patients with less symptomatic heart failure (Structured abstract). *Annals. of Internal. Medicine* 154:401-412.

4. Alehagen U, Rahmqvist M, Paulsson T, and Levin LA. (2008) Quality-adjusted life year weights among elderly patients with heart failure. *European Journal of Heart Failure* 10:1033-1039.

5. American College of Cardiology Foundation and American Heart Association Task Force on Practice Guidelines (ACCF/AHA/HRS). 2012 ACCF/AHA/HRS Focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. Journal of the American College of Cardiology 60, 1297-1313. 2012.

6. Anand,IS and VG Florea. End points in chronic heart failure clinical trials. Diaglogues in cardiovascular medicine 15[2], 81-101. 2010.

7. Arshad A, Moss AJ, Foster E, Padeletti L, Barsheshet A, Goldenberg I, Greenberg H, Hall WJ, McNitt S, Zareba W, Solomon S, and Steinberg JS. (2011) Cardiac resynchronization therapy is more effective in women than in men: The MADIT-CRT (multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy) trial. *Journal of the American College of Cardiology* 57:813-820.

8. Atwater BD, Dai D, Allen-Lapointe NM, Al-Khatib SM, Zimmer LO, Sanders GD, and Peterson ED. (2012) Is heart failure guideline adherence being underestimated? the impact of therapeutic contraindications. *American Heart Journal* 164:750-7e1.

9. Australian Department of Health and Ageing. Medicare Benefits Schedule Book. http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/72A85B0A56219B2DCA257B3B007ED3A4/$File/201305-MBS.pdf . 2013.

10. Australian Department of Health and Ageing. Pharmaceutical Benefits Schedule. http://www.pbs.gov.au/publication/schedule/2013/05/2013-05-01-general-schedule.pdf . 2013.

11. Australian Department of Health and Ageing. Prothesis List. http://www.health.gov.au/internet/main/publishing.nsf/Content/prostheses-list-pdf.htm . 2013.

12. Barsheshet A, Goldenberg I, Moss AJ, Eldar M, Huang DT, McNitt S, Klein HU, Hall WJ, Brown MW, Goldberger JJ, Goldstein RE, Schuger C, Zareba W, and Daubert JP. (2011) Response to

preventive cardiac resynchronization therapy in patients with ischaemic and nonischaemic cardiomyopathy in MADIT-CRT. *European Heart Journal* 32:1622-1630.

13. Barsheshet A, Moss AJ, Eldar M, Huang DT, Hall WJ, Klein HU, McNitt S, Steinberg JS, Wilber DJ, Zareba W, and Goldenberg I. (2011) Time-dependent benefit of preventive cardiac resynchronization therapy after myocardial infarction. *European. Heart Journal* 32:1614-1621.

14. Barsheshet A, Wang PJ, Moss AJ, Solomon SD, Al-Ahmad A, McNitt S, Foster E, Huang DT, Klein HU, Zareba W, Eldar M, and Goldenberg I. (2011) Reverse remodeling and the risk of ventricular tachyarrhythmias in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation TrialCardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 57:2416-2423.

15. Bertoldi EG, Polanczyk CA, Cunha V, Ziegelmann PK, Beck-Da-Silva L, and Rohde LE. (2011) Mortality reduction of cardiac resynchronization and implantable cardioverter-defibrillator therapy in heart failure: An updated meta-analysis. does recent evidence change the standard of care? *Journal of Cardiac Failure* 17:860-866.

16. Bittner V, Weiner DH, Yusuf S, Rogers WJ, McIntyre KM, Bangdiwala SI, Kronenberg MW, Kostis JB, Kohn RM, Guillotte M, and . (1993) Prediction of mortality and morbidity with a 6-minute walk test in patients with left ventricular dysfunction. SOLVD Investigators. *JAMA* 270:1702-1707.

17. Boston Scientific. Clinical summary: MADIT-CRT. 2011.

18. Bradshaw PJ, Stobie P, Briffa T, and Hobbs MS. (2013) Use and long-term outcomes of implantable cardioverter-defibrillators, 1990 to 2009. *American Heart Journal* 165:816-822.

19. Brenyo A, Link MS, Barsheshet A, Moss AJ, Zareba W, Wang PJ, McNitt S, Huang D, Foster E, Estes M, Solomon SD, and Goldenberg I. (2011) Cardiac resynchronization therapy reduces left atrial volume and the risk of atrial tachyarrhythmias in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the. American. College. of Cardiology* 58:1682-1689.

20. Buber J, Goldenberg I, Moss AJ, Wang PJ, McNitt S, Hall WJ, Eldar M, Barsheshet A, and Shechter M. (2012) Reduction in life-threatening ventricular tachyarrhythmias in statin-treated patients with nonischemic cardiomyopathy enrolled in the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 60:749-755.

21. Buber J, Klein H, Moss AJ, McNitt S, Eldar M, Padeletti L, Vogt J, Meine M, Brown MW, Barsheshet A, Zareba W, and Goldenberg I. (2011) Clinical course and outcome of patients enrolled in US and non-US centres in MADIT-CRT. *European Heart Journal* 32:2697-2704.

22. Cahalin LP, Mathier MA, Semigran MJ, Dec GW, and DiSalvo TG. (1996) The six-minute walk test predicts peak oxygen uptake and survival in patients with advanced heart failure. *Chest* 110:325-332.

23. Chen L and Hay JW. (2004) Cost-effectiveness of primary implanted cardioverter defibrillator for sudden death prevention in congestive heart failure. *Cardiovascular Drugs and Therapy* 18:161-170.

24. Chen S, Yin Y, and Krucoff MW. (2012) Effect of cardiac resynchronization therapy and implantable cardioverter defibrillator on quality of life in patients with heart failure: A meta-analysis. *Europace* 14:1602-1607.

25. Cleland JG, Daubert JC, Erdmann E, Freemantle N, Gras D, Kappenberger L, and Tavazzi L. (2005) The effect of cardiac resynchronization on morbidity and mortality in heart failure. *The New England journal of medicine* 352:1539-1549.

26. Cleland JG, Freemantle N, Daubert JC, Toff WD, Leisch F, and Tavazzi L. (2008) Long-term effect of cardiac resynchronisation in patients reporting mild symptoms of heart failure: a report from the CARE-HF study. *Heart* 94:278-283.

27. Daubert C, Gold MR, Abraham WT, Ghio S, Hassager C, Goode G, Szili-Torok T, and Linde C. (2009) Prevention of Disease Progression by Cardiac Resynchronization Therapy in Patients With Asymptomatic or Mildly Symptomatic Left Ventricular Dysfunction. Insights From the European Cohort of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) Trial. *Journal of the American College of Cardiology* 54:1837-1846.

28. European Society of Cardiology (ESC). ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Heart Journal 33, 1787-1847. 2013.

29. Feldman AM, De Lissovoy G, Bristow MR, Saxon LA, De Marco T, Kass DA, Boehmer J, Singh S, Whellan DJ, Carson P, Boscoe A, Baker TM, and Gunderman MR. (2005) Cost effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial. *Journal of the American College of Cardiology* 46:2311-2321.

30. Ford E, Adams J, and Graves N. (2012) Development of an economic model to assess the cost-effectiveness of hawthorn extract as an adjunct treatment for heart failure in Australia. *BMJ Open* 2.

31. Gohler A, Geisler BP, Manne JM, Kosiborod M, Zhang Z, Weintraub WS, Spertus JA, Gazelle GS, Siebert U, and Cohen DJ. (2009) Utility estimates for decision-analytic modeling in chronic heart failure - Health states based on New York Heart Association classes and number of rehospitalizations. *Value in Health* 12:185-187.

32. Gold MR, Linde C, Abraham WT, Gardiwal A, and Daubert JC. (2011) The impact of cardiac resynchronization therapy on the incidence of ventricular arrhythmias in mild heart failure. *Heart Rhythm* 8:679-684.

33. Goldenberg I, Hall WJ, Beck CA, Moss AJ, Barsheshet A, McNitt S, Polonsky S, Brown MW, and Zareba W. (2011) Reduction of the risk of recurring heart failure events with cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 58:729-737.

34. Goldenberg I, Moss AJ, Hall WJ, Foster E, Goldberger JJ, Santucci P, Shinn T, Solomon S, Steinberg JS, Wilber D, Barsheshet A, McNitt S, Zareba W, and Klein H. (2011) Predictors of response to cardiac resynchronization therapy in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). *Circulation* 124:1527-1536.

35. Goldenberg I, Moss AJ, McNitt S, Barsheshet A, Gray D, Andrews ML, Brown MW, Zareba W, Sze E, Solomon SD, and Pfeffer MA. (2010) Relation between renal function and response to cardiac resynchronization therapy in Multicenter Automatic Defibrillator Implantation Trial--Cardiac Resynchronization Therapy (MADIT-CRT). *Heart Rhythm.* 7:1777-1782.

36. Green CP, Porter CB, Bresnahan DR, and Spertus JA. (2000) Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *Journal of the American College of Cardiology* 35:1245-1255.

37. Havranek EP, Simon TA, L'Italien G, Smitten A, Brett Hauber A, Chen R, and Lapuerta P. (2004) The relationship between health perception and utility in heart failure patients in a clinical trial: Results from an OVERTURE substudy. *Journal of Cardiac Failure* 10:339-343.

38. Healey JS, Gula LJ, Birnie DH, Sterns L, Connolly SJ, Sapp J, Crystal E, Simpson C, Exner DV, Kus T, Philippon F, Wells G, and Tang AS. (2012) A randomized-controlled pilot study comparing ICD implantation with and without intraoperative defibrillation testing in patients with heart failure and severe left ventricular dysfunction: a substudy of the RAFT trial. *Journal of Cardiovascular Electrophysiology* 23:1313-1316.

39. Healey JS, Hohnloser SH, Exner DV, Birnie DH, Parkash R, Connolly SJ, Krahn AD, Simpson CS, Thibault B, Basta M, Philippon F, Dorian P, Nair GM, Sivakumaran S, Yetisir E, Wells GA, and Tang ASL. (2012) Cardiac resynchronization therapy in patients with permanent atrial fibrillation: Results from the Resynchronization for Ambulatory Heart Failure Trial (RAFT). *Circulation: Heart Failure* 5:566-570.

40. Heywood JT, Fonarow GC, Yancy CW, Albert NM, Curtis AB, Gheorghiade M, Inge PJ, McBride ML, Mehra MR, O'Connor CM, Reynolds D, and Walsh MN. (2010) Comparison of medical therapy dosing in outpatients cared for in cardiology practices with heart failure and reduced ejection fraction with and without device therapy report from IMPROVE HF. *Circulation: Heart Failure* 3:596-605.

41. Higgins SL, Hummel JD, Niazi IK, Giudici MC, Worley SJ, Saxon LA, Boehmer JP, Higginbotham MB, De Marco T, Foster E, and Yong PG. (2003) Cardiac Resynchronization Therapy for the Treatment of Heart Failure in Patients with Intraventricular Conduction Delay and Malignant Ventricular Tachyarrhythmias. *Journal of the American College of Cardiology* 42:1454-1459.

42. Hsu JC, Solomon SD, Bourgoun M, McNitt S, Goldenberg I, Klein H, Moss AJ, and Foster E. (2012) Predictors of super-response to cardiac resynchronization therapy and associated improvement in clinical outcome: The MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) study. *Journal of the American College of Cardiology* 59:2366-2373.

43. Knappe D, Pouleur AC, Shah AM, Cheng S, Uno H, Hall WJ, Bourgoun M, Foster E, Zareba W, Goldenberg I, McNitt S, Pfeffer MA, Moss AJ, and Solomon SD. (2011) Dyssynchrony, contractile function, and response to cardiac resynchronization therapy. *Circulation: Heart Failure* 4:433-440.

44. Kutyifa V, Kloppe A, Zareba W, Solomon SD, McNitt S, Polonsky S, Barsheshet A, Merkely B, Lemke B, Nagy VK, Moss AJ, and Goldenberg I. (2013) The influence of left ventricular ejection fraction on the effectiveness of cardiac resynchronization therapy: MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 61:936-944.

45. Kutyifa V, Pouleur AC, Knappe D, Al-Ahmad A, Gibinski M, Wang PJ, McNitt S, Merkely B, Goldenberg I, Solomon SD, Moss AJ, and Zareba W. (2013) Dyssynchrony and the risk of ventricular arrhythmias. *JACC: Cardiovascular Imaging* 6:432-444.

46. Kutyifa V, Zareba W, McNitt S, Singh J, Hall WJ, Polonsky S, Goldenberg I, Huang DT, Merkely B, Wang PJ, Moss AJ, and Klein H. (2013) Left ventricular lead location and the risk of ventricular arrhythmias in the MADIT-CRT trial. *European Heart Journal* 34:184-190.

47. Lim E, Brown A, Helmy A, Mussa S, and Altman DG. (2008) Composite Outcomes in Cardiovascular Research: A Survey of Randomized Trials. *Annals of Internal Medicine* 149:612-617.

48. Linde C, Abraham WT, Gold MR, John Sutton M, Ghio S, and Daubert C. (2008) Randomized Trial of Cardiac Resynchronization in Mildly Symptomatic Heart Failure Patients and in Asymptomatic Patients With Left Ventricular Dysfunction and Previous Heart Failure Symptoms. *Journal of the American College of Cardiology* 52:1834-1843.

49. Linde C, Gold M, Abraham WT, and Daubert JC. (2006) Rationale and design of a randomized controlled trial to assess the safety and efficacy of cardiac resynchronization therapy in patients with asymptomatic left ventricular dysfunction with previous symptoms or mild heart failure--the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) study. *American Heart Journal* 151:288-294.

50. Linde C, Gold M, Abraham WT, and Daubert JC. (2008) Baseline characteristics of patients randomized in The Resynchronization Reverses Remodeling In Systolic Left Ventricular Dysfunction (REVERSE) study. *Congest. Heart Fail.* 14:66-74.

51. Linde C, Mealing S, Hawkins N, Eaton J, Brown B, and Daubert JC. (2011) Cost-effectiveness of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure: insights from the European cohort of the REVERSE (Resynchronization Reverses remodeling in Systolic Left Ventricular Dysfunction). *European. Heart Journal* 32:1631-1639.

52. Lubitz SA, Leong SP, Fine N, Kramer DB, Singh J, and Ellinor PT. (2010) Effectiveness of cardiac resynchronization therapy in mild congestive heart failure: systematic review and meta-analysis of randomized trials (Structured abstract). *European. Journal of Heart Failure.* 12:360-366.

53. Martin DT, McNitt S, Nesto RW, Rutter MK, and Moss AJ. (2011) Cardiac resynchronization therapy reduces the risk of cardiac events in patients with diabetes enrolled in the multicenter automatic defibrillator implantation trial with cardiac resynchronization therapy (MADIT-CRT). *Circulation: Heart Failure* 4:332-338.

54. Medical Services Advisory Committee (MSAC). Implantable cardioverter defibrillators for prevention of sudden cardiac death. Assessment Report 32. 2006.

55. Medtronic. RAFT - Clinical report in support of pre-market approval. 2011.

56. Miller G, Randolph S, Forkner E, Smith B, and Galbreath AD. (2009) Long-term cost-effectiveness of disease management in systolic heart failure. *Med. Decis. Making* 29:325-333.

57. Moss AJ, Brown MW, Cannom DS, Daubert JP, Estes M, Foster E, Greenberg HM, Hall WJ, Higgins SL, Klein H, Pfeffer M, Wilber D, and Zareba W. (2005) Multicenter automatic

defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT): Design and clinical protocol. *Annals of Noninvasive Electrocardiology* 10:34-43.

58. Moss AJ, Hall WJ, Cannom DS, Klein H, Brown MW, Daubert JP, Estes III NAM, Foster E, Greenberg H, Higgins SL, Pfeffer MA, Solomon SD, Wilber D, and Zareba W. (2009) Cardiac-resynchronization therapy for the prevention of heart-failure events. *New England Journal of Medicine* 361:1329-1338.

59. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand (NHF/CSANZ). Guidelines for the prevention, detection and management of chronic heart failure in Australia: Updated July 2011. 2011.

60. National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. Technology Appraisal 95. 2007.

61. National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120). 2013.

62. Noyes K, Corona E, Veazie P, Dick AW, Zhao H, and Moss AJ. (2009) Examination of the effect of implantable cardioverter-defibrillators on health-related quality of life: Based on results from the multicenter automatic defibrillator trial-ii. *American Journal of Cardiovascular Drugs* 9:393-400.

63. Noyes K, Veazie P, Hall WJ, Zhao H, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2013) Cost-effectiveness of cardiac resynchronization therapy in the MADIT-CRT trial. *Journal of Cardiovascular Electrophysiology* 24:66-74.

64. Ozasa N, Morimoto T, Furukawa Y, Shizuta S, Nishiyama K, Kita T, and Kimura T. (2008) Effects of ICD implantation on quality-adjusted life years in patients with congestive heart failure. *International Journal of Cardiology* 123:213-216.

65. Packer M. (2001) Proposal for a new clinical end point to evaluate the efficacy of drugs and devices in the treatment of chronic heart failure. *J. Card Fail.* 7:176-182.

66. Pouleur AC, Knappe D, Shah AM, Uno H, Bourgoun M, Foster E, McNitt S, Hall WJ, Zareba W, Goldenberg I, Moss AJ, Pfeffer MA, and Solomon SD. (2011) Relationship between improvement in left ventricular dyssynchrony and contractile function and clinical outcome with cardiac resynchronization therapy: The MADIT-CRT trial. *European Heart Journal* 32:1720-1729.

67. Pradelli L, Iannazzo S, and Zaniolo O. (2009) The cost effectiveness and cost utility of valsartan in chronic heart failure therapy in ITALY: A probabilistic markov model. *American Journal of Cardiovascular Drugs* 9:383-392.

68. Rector,T. Overview of the Minnesota Living with Heart Failure Questionnaire. http://www.license.umn.edu/Products/Minnesota-Living-With-Heart-Failure-Questionnaire__Z94019.aspx . 2005. University of Minnesota.

69. Reddy HK, Weber KT, Janicki JS, and McElroy PA. (1988) Hemodynamic, ventilatory and metabolic effects of light isometric exercise in patients with chronic heart failure. *Journal of the American College of Cardiology* 12:353-358.

70. Ribeiro RA, Stella SF, Camey SA, Zimerman LI, Pimentel M, Rohde LE, and Polanczyk CA. (2010) Cost-effectiveness of implantable cardioverter-defibrillators in Brazil: Primary prevention analysis in the public sector. *Value in Health* 13:160-168.

71. Ruwald MH, Ruwald ACH, Jons C, Alexis J, McNitt S, Zareba W, and Moss AJ. (2013) Effect of metoprolol versus carvedilol on outcomes in MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy). *Journal of the American College of Cardiology* 61:1518-1526.

72. Sanders GD, Kong MH, Al-Khatib SM, and Peterson ED. (2010) Cost-effectiveness of implantable cardioverter defibrillators in patients (greater-than or equal to)65 years of age. *American Heart Journal* 160:122-131.

73. Santangeli P, Di Biase L, Pelargonio G, Dello Russo A, Casella M, Bartoletti S, David Burkhardt J, Mohanty P, Santarelli P, and Natale A. (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis. *Journal of Interventional Cardiac Electrophysiology* 32:125-135.

74. Singh JP, Klein HU, Huang DT, Reek S, Kuniss M, Quesada A, Barsheshet A, Cannom D, Goldenberg I, McNitt S, Daubert JP, Zareba W, and Moss AJ. (2011) Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trial-cardiac resynchronization therapy (MADIT-CRT) trial. *Circulation* 123:1159-1166.

75. Solomon SD, Foster E, Bourgoun M, Shah A, Viloria E, Brown MW, Hall WJ, Pfeffer MA, and Moss AJ. (2010) Effect of cardiac resynchronization therapy on reverse remodeling and relation to outcome: Multicenter automatic defibrillator implantation trial: Cardiac resynchronization therapy. *Circulation* 122:985-992.

76. Tang AS, Wells GA, Arnold M, Connolly S, Hohnloser S, Nichol G, Rouleau J, Sheldon R, and Talajic M. (2009) Resynchronization/defibrillation for ambulatory heart failure trial: Rationale and trial design. *Current Opinion in Cardiology* 24:1-8.

77. Tang ASL, Wells GA, Talajic M, Arnold MO, Sheldon R, Connolly S, Hohnloser SH, Nichol G, Birnie DH, Sapp JL, Yee R, Healey JS, and Rouleau JL. (2010) Cardiac-resynchronization therapy for mild-to-moderate heart failure. *New England Journal of Medicine* 363:2385-2395.

78. Tu R, Zhong G, Zeng Z, Wu W, Wu H, Cao X, and Aung LHH. (2011) Cardiac resynchronization therapy in patients with mild heart failure: A systematic review and meta-analysis of randomized controlled trials. *Cardiovascular Drugs and Therapy* 25:331-340.

79. Van Rees JB, De Bie MK, Thijssen J, Borleffs CJ, Schalij MJ, and van EL. (2011) Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. *Journal of the American College of Cardiology* 58:995-1000.

80. Veazie PJ, Noyes K, Li Q, Hall WJ, Buttaccio A, Thevenet-Morrison K, and Moss AJ. (2012) Cardiac resynchronization and quality of life in patients with minimally symptomatic heart failure. *Journal of the American College of Cardiology* 60:1940-1944.

81. Wells G, Parkash R, Healey JS, Talajic M, Arnold JM, Sullivan S, Peterson J, Yetisir E, Theoret-Patrick P, Luce M, and Tang ASL. (2011) Cardiac resynchronization therapy: A meta-analysis of randomized controlled trials. *CMAJ* 183:421-429.

82. Yao G, Freemantle N, Calvert MJ, Bryan S, Daubert JC, and Cleland JGF. (2007) The long-term cost-effectiveness of cardiac resynchronization therapy with or without an implantable cardioverter-defibrillator. *European Heart Journal* 28:42-51.

83. Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, and Wheelan K. (2003) Combined Cardiac Resynchronization and Implantable Cardioversion Defibrillation in Advanced Chronic Heart Failure: The MIRACLE ICD Trial. *Journal of the American Medical Association* 289:2685-2694.

84. Zanolla L and Zardini P. (2003) Selection of endpoints for heart failure clinical trials. *European Journal of Heart Failure* 5:717-723.

85. Zareba W. (2010) Comparison of clinical trials evaluating cardiac resynchronization therapy in mild to moderate heart failure. *Cardiology Journal* 17:543-548.

86. Zareba W, Klein H, Cygankiewicz I, Hall WJ, McNitt S, Brown M, Cannom D, Daubert JP, Eldar M, Gold MR, Goldberger JJ, Goldenberg I, Lichstein E, Pitschner H, Rashtian M, Solomon S, Viskin S, Wang P, and Moss AJ. (2011) Effectiveness of Cardiac Resynchronization Therapy by QRS Morphology in the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT). *Circulation* 123:1061-1072.