

A09/S/a

**2013/14 NHS STANDARD CONTRACT
FOR CARDIOLOGY: IMPLANTABLE CARディオVERTER DEFIBRILLATOR (ICD)
AND CARDIAC RESYNCHRONISATION THERAPY (CRT) (ADULT)**

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A09/S/a
Service	Cardiology: Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronisation Therapy (CRT) (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Sudden cardiac death (SCD) occurs in approximately 50,000–70,000 people annually in the UK and represents the largest proportion (60%) of the deaths attributable to ischaemic heart disease.

- The survival rates for out-of-hospital sudden cardiac episodes are less than 5% in most industrialised countries, including the UK
- Sudden cardiac death (SCD) is due to ventricular fibrillation or ventricular tachycardia in about 80% of cases
- Bradyarrhythmias or undetermined rhythm are found in the remaining cases
- SCD is the first recognised arrhythmic event in 85-90% of cases, so most of these deaths have no warning
- Patients who survive a life threatening ventricular arrhythmia are at high risk of further, likely fatal, events: without treatment, approximately 40% will die within 2 years

Patients who survive either ventricular fibrillation or sustained ventricular tachycardia are at high risk of SCD. However, this group of patients is very much in the minority as most episodes of SCD occur in patients with no previous arrhythmic episodes. It is therefore important to be able to identify those patients at risk of SCD yet to have an event (primary prevention).

People at highest risk of SCD are those with:

- a previous myocardial infarction (MI)

- congestive cardiac failure
- left ventricular (LV) ejection fraction (EF) < 35%
- selected people with surgically-corrected congenital heart disease (e.g. tetralogy of Fallot)
- selected people with inherited conditions that predispose to life threatening ventricular arrhythmias (such as long QT syndrome, Brugada syndrome and hypertrophic cardiomyopathy)

In people diagnosed with heart failure, sudden cardiac death occurs at 6-9 times the rate of the general population. People who have had a heart attack have a sudden cardiac death rate that is 4-6 times the general population.

Left ventricular ejection fraction (EF) is a measure of cardiac function and low EF remains the single most important risk factor for overall mortality from SCD. There is a strong relationship between EF and one-year mortality. One in thirteen people with an EF < 30% (normal 60%) will experience SCD.

The greatest opportunity for SCD prevention is in patients with mild to moderate heart failure symptoms (NYHA class II-III, meaning a mild to moderate level of breathlessness on exertion). This group of patients have, overall, a good quality of life and SCD is the main reason that their lives are shortened.

SCD is due to ventricular tachycardia or fibrillation in >80% of cases. In the event of a cardiac arrest time is critical; each minute of delay before defibrillation reduces survival rates by about 10%. Implantable cardioverter defibrillators (ICDs) offer a therapeutic option. They recognise life-threatening heart rhythms and deliver immediate treatment using rapid painless pacing or emergency internal shock therapy.

Several prospective multicentre clinical trials have documented improved survival using ICDs in high-risk patients with LV dysfunction due to a prior heart attack and/or non-ischaemic cardiomyopathy. ICD therapy compared with conventional or traditional antiarrhythmic drug therapy has been associated with mortality reductions from 23% to 55% depending on the risk group participating in the trial, with the improvement in survival due almost exclusively to reduction in SCD. The trials may be subcategorised into two types: primary prevention (prophylactic) trials in which the subjects have not experienced a life-threatening arrhythmia or a symptomatic equivalent and secondary prevention trials involving subjects who have had an aborted cardiac arrest or unexplained syncope with work-up suggesting a high probability that a ventricular tachyarrhythmia was the cause of the syncope.

In the UK, we are good at dealing with patients who survive a cardiac arrest, but the 2011 Cardiac Rhythm Management UK National Clinical Audit Report shows that only a minority of potentially eligible primary prevention patients are implanted with an ICD.

Cardiac Resynchronisation Therapy (CRT)

Heart failure is a complex syndrome that can result from any structural or functional cardiac disorder that impairs the heart's ability to function efficiently as a pump to support physiological circulation. The incidence and prevalence of heart failure increase steeply with age and the average age at first diagnosis is 76 years. The incidence of heart failure in the UK is 140 per 100,000 men and 120 per 100,000 women. Around 3% of people aged 65–74 years have heart failure; this increases to about 7% of those aged 75–84 years and to just over 14% in those aged 85 years and older. The prevalence of heart failure in the UK is 40 per 1000 in men and 30 per 1000 in women.

Heart failure has a poor prognosis, with about 40% of patients dying within 1 year of diagnosis. More severely ill patients are more likely to die because of pump failure (congestive heart failure), but those with less severe heart failure (NYHA class II–III as above) are more likely to experience sudden cardiac death. Treatment for heart failure aims to improve life expectancy and quality of life. Heart failure should initially be managed pharmacologically in accordance with the NICE clinical guideline 'Chronic heart failure: management of chronic heart failure in adults in primary and secondary care' (NICE clinical guideline 5 (www.nice.org.uk/nicemedia/pdf/CG5NICEguideline.pdf)).

However, as the condition becomes more severe, symptoms may no longer be controlled by pharmacological treatment.

Some patients with severe heart failure and impaired left ventricular systolic function ($EF < 35\%$) also have electrical conduction abnormalities that result in poorly coordinated, dyssynchronous left ventricular filling and contraction. This dyssynchrony manifests on the 12 lead electrocardiogram (ECG) as QRS prolongation $> 120\text{ms}$ with a left bundle branch block (LBBB) morphology. Many echocardiographic parameters have also been reported. CRT (also referred to as biventricular pacing) is a non-pharmacological therapy that aims to correct the dyssynchrony and thus is an option for symptomatic patients with poor LV function and QRS prolongation $> 120\text{ms}$. Although primarily used to improve symptoms and quality of life, CRT also improves prognosis.

A standard CRT pacing system (CRT-P) consists of a right ventricular lead, a left ventricular lead and an atrial lead. An ICD function can be included to defibrillate the heart internally should an acute arrhythmic event occur; in this case, the device is known as a CRT-D device.

Evidence Base for ICDs

A number of randomised controlled trials (RCTs) comparing devices to medical management have been published supporting the use of ICDs in high risk patients.

Secondary prevention trials include antiarrhythmics versus implantable defibrillators (AVID) (*New Engl J Med* 1997; **337**: 1576-83), Canadian implantable defibrillator study (CIDS) (*Circulation* 2000; **101**:1297-302) and cardiac arrest study Hamburg

(CASH) (*Circulation* 2000; **102**: 748-54) plus a meta-analysis (*Eur Heart J* 2000; **21**: 2071-8). These trials enrolled cardiac arrest survivors who had suffered ventricular fibrillation or haemodynamically-compromising ventricular tachycardia. Many, but not all, had impaired LV function. Both ischaemic and non-ischaemic aetiologies were included; however, cardiac arrest in the setting of acute ST elevation MI was an exclusion. ICDs reduced mortality by 13-31% over 3 year follow-up (25% in the meta-analysis, absolute risk reduction 8%, NNT 13)

Primary prevention trials include multicentre automatic defibrillator implantation trial (MADIT) (*New Engl J Med* 1996; **335**: 1933-40) and multicentre unsustained tachycardia trial (MUSTT) (*New Engl J Med* 1999; **341**: 1882-90), MADIT-II (*New Engl J Med* 2002; **346**: 877-83) and sudden cardiac death in heart failure (SCD-HeFT) (*New Engl J Med* 2005; **352**: 225-37). MADIT, MUSTT and MADIT-II enrolled patients with ischaemic heart disease (IHD), whereas SCD-HeFT enrolled both IHD and non-ischaemic cardiomyopathy patients. For patients with IHD, primary prevention ICDs reduced total mortality after 3 year FU by 20-59%. This reduction was sustained over 8 year follow-up (*Circulation* 2010; **122**: 1265-71). The non-ischaemic patients in SCD-HeFT had a 3 year mortality reduction of 25%. In the MADIT trial the 3 year absolute risk reduction was 25% (NNT 4).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance in Technical Appraisal TA95 (guidance.nice.org.uk/TA95/Guidance) on the use of ICDs. The Institute has stated that ICDs should be routinely considered for both primary and secondary prevention of life threatening arrhythmias. The guidance was drawn up before the findings of the SCD-HeFT trial could be assimilated and thus only address primary prevention in IHD and not dilated cardiomyopathy. The 2008 European and North American guidelines follow the SCD-HeFT criteria and support prophylactic ICD implantation in non-ischaemic cardiomyopathy patients with EF<35% and New York Heart Association (NYHA) class II-III heart failure symptoms (*Circulation* 2008; **117**: 2820-40). The 2012 European Society of Cardiology guidelines for heart failure do not differentiate their recommendations on the basis of the aetiology of the LV impairment. This guidance has been taken up to varying degrees by UK Primary Care Trusts (PCTs).

The defibrillator in acute myocardial infarction trial (DINAMIT) (*N Engl J Med* 2004; **351**: 2481-8) and IRIS (*N Engl J Med* 2009; **361**: 1427-36) trials have shown that primary prevention ICDs inserted within 40 days of an acute myocardial infarction do not confer a survival benefit, thus primary prevention ICDs are reserved for eligible IHD patients with remote myocardial infarction, often several years, as patients can become increasingly at risk due to adverse remodelling of the LV.

ICDs have also been shown to be beneficial in terms of preventing sudden cardiac death and/or terminating potentially fatal ventricular arrhythmias among patients with hypertrophic cardiomyopathy (HCM). HCM is the commonest cause of non-traumatic sudden death in individuals < 35 years and among athletes. ICD therapy is also the treatment of choice in high-risk patients with other forms of cardiomyopathy such as arrhythmogenic right ventricular cardiomyopathy. ICDs are also used in congenital long QT syndrome and other primary electrical heart problems.

Evidence Base for CRT

The evidence base to support the use CRT is large, robust and growing rapidly. There are multiple high quality multicentre randomised controlled studies demonstrating remarkable improvements in quality of life, left ventricular function and prognosis in appropriately selected patients with symptomatic (multisite stimulation in cardiomyopathies (MUSTIC), comparison of medical therapy, pacing and defibrillation in chronic heart failure (COMPANION), cardiac resynchronisation in heart failure (CARE-HF) studies) and, recently, minimally-symptomatic heart failure (resynchronisation for ambulatory heart failure (RAFT), resynchronisation reverses remodelling in systolic left ventricular dysfunction (REVERSE), MADIT-CRT) studies. In addition, more recent data extends the evidence base for biventricular pacing to selected patients requiring long-term ventricular-based anti-bradycardia pacing in the presence of poor left ventricular function.

Early trials of CRT enrolled patients with NYHA III-IV heart failure despite optimal medical therapy, EF < 35%, a dilated left ventricle and evidence of electrical dyssynchrony defined by a wide QRS (*N Engl J Med* 2001; **344**: 873–80, *N Engl J Med* 2002; **346**: 1902–5, *JAMA* 2003; **289**: 2685–94).

These trials showed that CRT improved symptoms, quality of life and exercise tolerance as assessed by six-minute walk testing.

The COMPANION trial included 1520 patients with NYHA III-IV heart failure, EF < 35% and QRS duration > 120ms (*N Engl J Med* 2004; **350**: 2140-50). Patients were randomly assigned to one of three groups: optimal medical therapy (OMT) alone; OMT and CRT-P or OMT and CRT-D. CRT reduced the combined endpoint of risk of death from any cause or first admission. CRT-D reduced the secondary endpoint of all cause mortality. COMPANION was not designed or powered to compare CRT-P to CRT-D.

The CARE-HF trial included 813 patients with NYHA III-IV heart failure and EF < 35% and QRS duration > 120ms (*N Engl J Med* 2005; **352**: 1539-49). Patients were randomly assigned to optimal medical therapy (OMT) or CRT-P and OMT. The mean follow up time was 29 months. CRT-P was associated with a 37% relative risk reduction of the composite primary endpoint, namely, time to death from any cause or an unplanned admission for a major cardiovascular event. CRT-P also reduced all cause mortality by 36% which was confirmed at 36 months follow up. CARE-HF also showed that CRT-P provided a sustained effect on reverse remodelling of left ventricular function, which increased in magnitude from 29 to 36 months of follow up.

On the basis of the above trial data, NICE issued UK guidelines for CRT implantation in 2007 (www.nice.org.uk/TA120). The advice did not cover patients with chronic atrial fibrillation, although as many as one third of heart failure patients suffer from this arrhythmia. Subsequent publications support the use of CRT in heart failure patients with atrial fibrillation, including those undergoing AV node ablation for ventricular rate control (*J Cardiovasc Electrophysiol* 2005;**16**: 1160-5). This group has been included in the ESC 2012 guidelines (*Eur Heart J* 2012; **33**: 1787-847).

Patients with impaired left ventricular function may also suffer harm, including increased mortality, from single site right ventricular pacing that induces mechanical dyssynchrony (*JAMA* 2002; **288**: 3115-23). When there is a bradycardia pacing indication, it is increasingly felt that these patients should receive CRT-P (*Eur Heart J* 2012; **33**: 1787-847).

After the convincing results in patients with severe heart failure, the effect of CRT on morbidity and mortality was assessed in patients with mildly symptomatic or asymptomatic heart failure, a severely depressed LVEF and wide QRS. Three randomised prospective trials have been undertaken. In the REVERSE trial, 610 patients in NYHA class I-II, EF < 40%, QRS duration > 120ms underwent implantation and were randomised to CRT programmed ON or CRT programmed OFF (*J Am Coll Cardiol* 2008; **52**: 1834-43). Non-ischaemic patients improved their EF more than ischaemic patients. Patients with QRS duration > 150ms benefitted more from CRT. In the MADIT-CRT trial, 1820 patients with mildly symptomatic heart failure, EF < 30% and QRS duration > 130ms were randomly assigned to CRT-D or ICD (*N Engl J Med* 2009; **361**: 1329-38). After a mean follow up of 2.4 years, survival free of heart failure events was higher in the CRT-D group, due to reduced heart failure episodes. Patients with QRS duration > 150ms seemed to benefit the most. The RAFT trial randomly assigned 1798 patients with NYHA class II-III, LVEF < 30%, QRS duration > 120ms to ICD versus CRT-D (*N Engl J Med* 2010; **363**: 2385-95). The results confirmed the findings of fewer deaths of heart failure admissions in the CRT group. In contrast to REVERSE and MADIT-CRT, there was also a significant reduction in all cause mortality.

The data from REVERSE, MADIT-CRT and RAFT are convincing for NYHA II patients, especially those with QRS duration > 150ms. CRT in NYHA I patients is not yet adequately supported due to the small numbers of patients enrolled. The 2010 European Society of Cardiology (ESC) Guidelines update recommends the use of CRT in NYHA class II patients (*Eur Heart J* 2010; **31**: 2677-87) which is endorsed as a class I indication in the 2012 guidelines (*Eur Heart J* 2012; **33**: 1787-847).

SUMMARY

ICDs have been shown to be an effective therapy in patients who have suffered a life-threatening heart rhythm disturbance or who have been shown to be at risk of developing such an arrhythmia.

The majority of patients in these groups have impaired heart function due either to a previous heart attack or other form of heart muscle disease.

In the UK the implantation rate of such devices in survivors of cardiac arrests is high but only a minority of patients who are at risk of, but yet to experience an arrhythmia, receive an ICD.

CRT devices can improve quality of life and prognosis in patients with heart failure and abnormal electrical conduction within the ventricles.

2. Scope

2.1 Aims and objectives of service

Aims

The core aim is to improve patient longevity and/or quality of life with the minimum risk of harm and maximum amount of patient support.

Objectives

The service will deliver the aim of reducing sudden cardiac death and improving quality of life by the following actions:

- Offer timely assessment of patients who present with potentially life-threatening ventricular arrhythmias or cardiac arrest survivors
- Offer assessment of potentially eligible patients for primary prevention ICDs through a dedicated screening programme
- Deliver appropriate referral streams for eligible patients to an implanting physician
- Provide suitable facilities for safe and high quality ICD and CRT implantation
- Provide facilities and staff for regular device follow-up (on-site and remote access)
- Offer referral to supporting services (on site or in neighbouring tertiary centre) including catheter ablation, heart failure management, revascularisation and psychological support
- Provide rolling audit and submission of data to National Institute for Cardiovascular Outcomes Research (NICOR)
- Facilitate access to patient support groups

2.2 Service description/care pathway

Patients requiring ICD implantation on a secondary prevention basis will usually have presented to a cardiology or acute medical service with symptomatic arrhythmias. Secondary care services will have explicit protocols in place to allow identification of these individuals, who are at high risk of SCD and to facilitate their prompt referral to an ICD service either locally or to a tertiary centre.

Patients requiring ICD implantation on a primary prevention have historically been harder to identify. This problem is being exacerbated by pressure on cardiology services to refer patients with established left ventricular dysfunction back to primary care for follow up. Individuals suitable for ICD implantation are often minimally symptomatic on a day to day basis. Some of these patients can be identified from the population with ischaemic and non-ischaemic left ventricular dysfunction through heart failure, general cardiology or primary care services, however, many patients, due to their lack of symptoms may not be under regular review. Nevertheless, the

risk of sudden death in such patients does increase with time due to adverse remodelling, dilatation of the LV and development of a broad QRS complex. Local protocols and guidelines will need to be in place to identify appropriate individuals and to facilitate their prompt referral to an ICD service for assessment.

Assessment of suitability for ICD implantation in individuals with rarer disorders such as hypertrophic cardiomyopathy, congenital long QT syndrome, arrhythmogenic right ventricular cardiomyopathy and Brugada syndrome is often challenging. These individuals will be referred to a specialist service for detailed assessment (see Inherited Cardiac Conditions Service Specification).

Patients eligible for CRT will usually be identified in the outpatient setting as one of the requirements is the need to be on stable optimal therapy. Some will be under review in general cardiology and heart failure clinics whereas many will be under general medical follow-up or in primary care where they are less likely to be identified. Inevitably, some patients will present as emergency admissions with acute decompensation and may require inpatient CRT treatment prior to hospital discharge. Identification of eligible patients may be facilitated by the use of screening programmes that combine ECG, echocardiography and symptom data.

Following ICD and CRT implantation, lifelong follow up in a dedicated ICD follow up clinic is mandatory and the majority of patients should also be under long term follow up with their secondary care cardiologist. Pathways should be established to facilitate access to specialist support from trained arrhythmia nurses or clinical psychologists.

The published data are consistent with a continuous risk variable favouring high volume operators in high volume institutions. There is no clear cut-off between high and low risk, but the data would support a minimum implantation number of ≥ 30 ICDs per cardiologist per year in an institution implanting ≥ 60 first ICDs per year. This is consistent with the recommendation for at least 2 implanters per centre.

In order to assess patients for ICD/CRT therapy, centres will have access to:

- Echocardiography for accurate ejection fraction and dyssynchrony
- Angiography
- Cardiac Magnetic Resonance Imaging (MRI)
- Electrophysiology studies
- Revascularisation (coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)) before or after, device implantation
- Anaesthetic support for sedation and general anaesthesia

Patients surviving cardiac arrest or sustained ventricular tachycardia require access to an electrophysiology service. Primary prevention patients not requiring electrophysiology study (MI >4 weeks previously, EF $\leq 30\%$, QRS $> 120\text{ms}$) should represent approximately 20% of implants (on current estimates).

Requirements for lead extraction

Lead extraction involves the complete removal of a pacemaker or ICD lead with

specialised tools not normally used for implantation. The current indications for lead extraction are detailed in the 2009 Heart Rhythm Society Expert Consensus.

Lead extraction will be performed by two operators, at least one of whom must have undergone suitable training including 20 procedures under the direct supervision of an operator with an experience of >100 lead extractions. The procedures will normally be performed under general anaesthetic in a centre that has immediate access to cardiothoracic surgery. It is not required, therefore, that all CRT/ICD implanting centres should provide a lead extraction service. Centres will maintain a database of extraction procedures, indications and complications for clinical governance. (see also Heart Rhythm UK guidance).

Implantable device follow-up standards

Following ICD and CRT implantation, lifelong follow up in a dedicated ICD follow up clinic is mandatory and the majority of patients should also be under long term follow up with their secondary care cardiologist. Pathways should be established to facilitate access to specialist support from trained arrhythmia nurses or clinical psychology.

Patients with cardiac rhythm management devices require life-long follow-up with specialised medical and technical expertise and equipment. This will be performed in accordance with published “Heart Rhythm UK Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults – January 2013.”

Arrangements for staffing for 24 hour cover will be in place for all device patients and should include cardiologists with training in follow up of devices who have an ongoing commitment in this area. This is particularly important for ICD patients where device-related and arrhythmia complications occur frequently and can be life-threatening. For secondary care centres these arrangements will be provided by and with the agreement of the regional centre, with a clearly defined and documented protocol.

Follow-up will be performed at nationally accepted intervals (within 2 months of implantation and then max. 6 monthly). Patients will have urgent follow up if they report symptoms which may be associated with their device.

In-clinic follow-up will include:

- Wound review
- Recorded patient rhythm data (including atrial fibrillation or ventricular arrhythmias which may require medical input)
- Device checks – battery, lead impedance, pacing thresholds, sensitivity
- Access to specialised echocardiography services for CRT optimisation when required
- Access to specialised electrophysiology services for management of atrial and ventricular arrhythmias when required
- Data recording in a form which can be transferred to another centre

- Psychological support and early identification of distress
- Communication with cardiologists, heart failure team and general practitioners as indicated

End of Patient Life Management

Device implantation centres are strongly encourage to follow a local policy for the management of end of patient life.

All device follow up centres (including those which only follow up pacemakers) should have a policy in place for deactivation of ICD function in ICD and CRT-D devices which should include the facility for domiciliary visits.

Device therapy termination should be a consensus between the physician normally responsible for patient care e.g. oncologist, device consultant, GP, device physiologist, the patient and where possible a representative for the patient (e.g. a relative).

Different levels of device therapy termination should be considered specific to the individual case and informed consent must be documented.

SUMMARY

Identification of patients who will benefit from ICDs and CRT is important and involves all levels of care from primary through to tertiary.

Standards for implantation and follow-up of such devices have been set by Heart Rhythm UK.

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

*Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP practice in England.

Specifically the service is targeted to:

- Patients who survive either ventricular fibrillation or sustained ventricular tachycardia for secondary prevention ICDs
- Selected individuals deemed to be a high risk of SCD for primary prevention ICDs
- Patients with symptomatic heart failure, LVEF < 35% and QRS duration > 120ms

for CRT

2.4 Any acceptance and exclusion criteria

Acceptance

The service will accept referrals from secondary care cardiologists and physicians.

Most patients will have symptomatic or recently symptomatic heart failure and will be identified from general cardiology or heart failure follow up services by secondary care cardiologists or heart failure specialist nurses. However, individuals suitable for ICD implantation are often minimally symptomatic on a day to day basis and may not be under regular follow-up. Some patients will be identified as part of their assessment to receive a bradycardia pacemaker or implantable cardioverter defibrillator. Local pathways should be in place to streamline the identification and referral of patients to an appropriate service. Appropriate patient counselling is vital and involvement of the patient in device allocation imperative.

Referral Criteria

The assessment of patients potentially requiring CRT and the subsequent selection and implantation of the device are complex and challenging areas of care and will be provided only in centres with appropriate training and experience of complex device therapy. Appropriate selection of patients requires multidisciplinary working with interaction between cardiologists expert in the management of arrhythmias and device therapy, in imaging (particularly echocardiography and MRI) and heart failure. Target patient groups for ICDs are those with ischaemic and non-ischaemic cardiomyopathy who have survived cardiac arrest and life-threatening ventricular arrhythmias, or are at high risk of doing so due to the presence of low left ventricular ejection fraction. Target patients for CRT are those with symptomatic heart failure on optimal drug therapy, severely impaired left ventricular function and left ventricular dyssynchrony (through LBBB or single site right ventricular (RV) pacing) manifest as a QRS wider than 120ms. Some patients will be eligible for both CRT and an ICD.

For ICDs

For secondary prevention, that is, for patients who present, in the absence of a treatable cause, with one of the following:

- Having survived a cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation
- Spontaneous sustained VT causing syncope or significant haemodynamic compromise
- Sustained VT without syncope or cardiac arrest, and who have an EF of < 35%; no worse than NYHA class III.

For primary prevention of arrhythmias, that is, for patients who have:

- Left ventricular dysfunction with an ejection fraction (EF) of < 35% (no worse than NYHA class III) (ESC Guidelines)
- A familial cardiac condition with a high risk of sudden death, including congenital

long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or

arrhythmogenic right ventricular cardiomyopathy, or have undergone surgical repair of congenital heart disease

For CRT

In 2003 NICE Clinical Guideline (CG05) said that for patients with chronic heart failure, CRT should be considered in selected patients with left ventricular systolic dysfunction (EF \leq 35%), drug refractory symptoms, and a QRS duration $>$ 120ms.

NICE Technical Appraisal 120 (May 2007) updated recommendations on the use of CRT. NICE said that CRT-D may be considered for people with heart failure if:

- Their heart failure is suitable for treatment with a pacing device
- And it is also suitable for treatment with an ICD

In 2012 the European Society of Cardiology published updated guidelines on CRT. It set out key objectives for reduced mortality and improved morbidity (including quality of life and reduced hospitalisation). It recommended CRT as a treatment for people with class III-IV heart failure where the following circumstances apply:

- They are taking optimal drug treatment
- An ECG shows a QRS duration of \geq 120 ms with a LBBB morphology
- An ECG shows a QRS duration of \geq 150 ms irrespective of QRS morphology
- The EF is \leq 35%

It recommended CRT as a treatment for people with class II heart failure where the following circumstances apply:

- They are taking optimal drug treatment
- An ECG shows a QRS duration of \geq 130 ms with a LBBB morphology
- An ECG shows a QRS duration of \geq 150 ms irrespective of QRS morphology
- The EF is \leq 30%

Individuals with atrial fibrillation also benefit from CRT provided that adequate ventricular rate control is achieved with either pharmacologic treatment or catheter ablation of the AV node.

The incorporation of a left ventricular pacing lead into a pacing system to treat bradycardia can be justified if (a) the patient has symptomatic heart failure or (b) the patient has severe asymptomatic left ventricular dysfunction and a life expectancy greater than 1-2 years and will unavoidably require a high burden ($>$ 40% of all beats) of ventricular pacing.

Exclusions

The use of echocardiographic or other imaging criteria to select patients for CRT on the basis of presence or absence of dyssynchronous LV contraction cannot currently be justified, other than to demonstrate the presence of significant left ventricular dysfunction.

SUMMARY

Protocols should be in place to identify patients who would benefit from ICDs and CRT devices

For ICDs, devices should be offered to patients who have survived a cardiac arrest or an arrhythmia associated with haemodynamic compromise (collapse / low blood pressure).

ICDs should also be considered for primary prevention for patients who have poor heart function (ejection fraction <35%) and those with inherited electrical conditions.

CRT devices should be considered for patients with symptomatic heart failure who have poor heart function and slow electrical conduction within the ventricles (left bundle branch block). Such devices may also incorporate an ICD function.

2.5 Interdependencies with other services

Co-located services –

- Cardiac intensive care unit
- Anaesthetic support for sedation and general anaesthesia
- Echocardiography for accurate ejection fraction and dyssynchrony

Interdependent services –

- Cardiac surgery

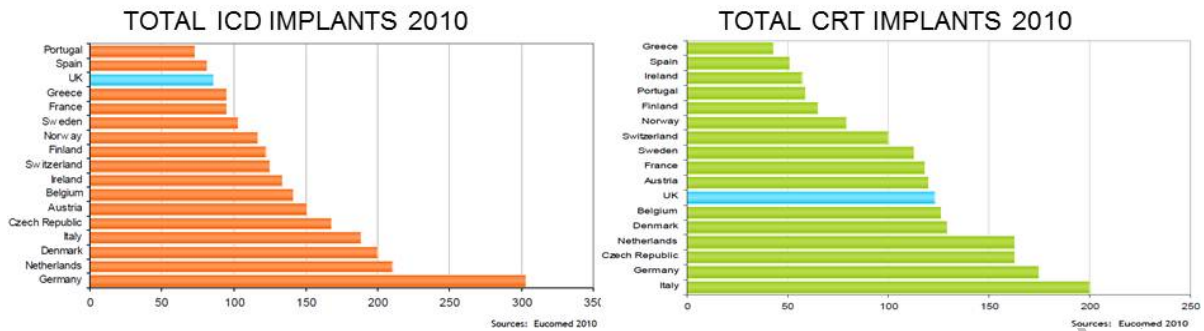
Related services –

- Cardiac rehabilitation services, Genetics services

2.6 Current patient volumes and expected trends

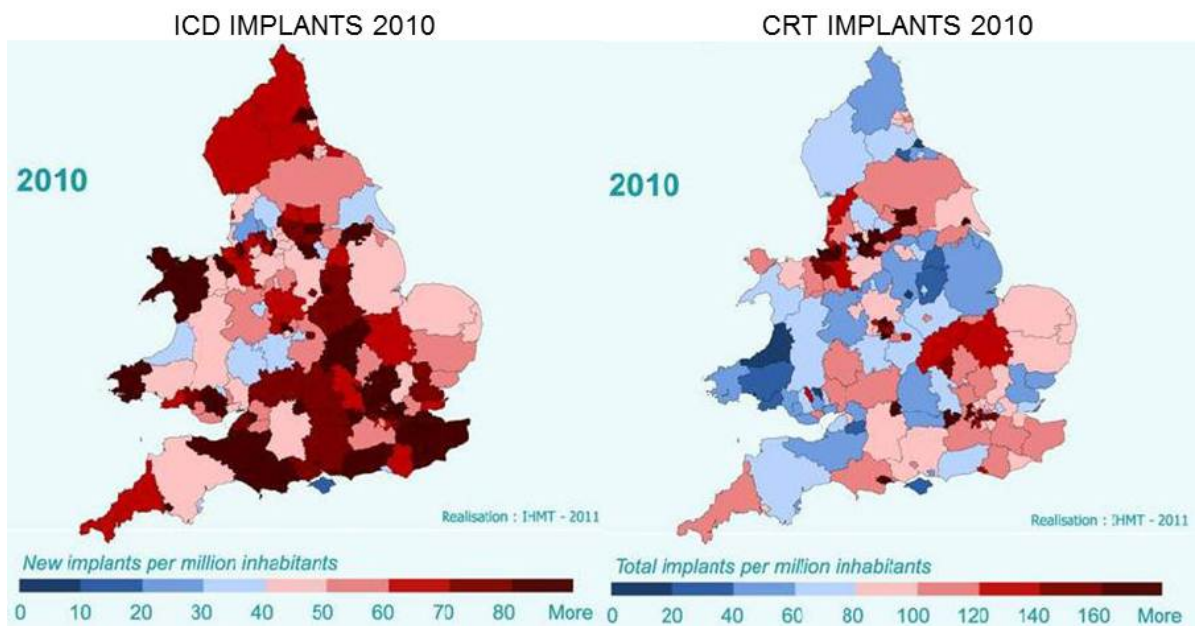
Current levels of ICD and CRT implantation are increasing in England. The new ICD implant rate in 2010 increased to 72 per million population, an increase of 14.8% compared to 2009 (Cardiac Rhythm Management Audit 2010). However, whilst this increase is encouraging, the UK implant rate still currently falls well below the mean for Europe of 169 per million) and only Spain and Portugal have rates below the UK target rate of 100 per million.

The total CRT implant rate in England also increased by 14.9% in 2010 to 114 per million population. Comparison with Europe is better, but the UK remains below the European mean implant rate of 133 per million and the UK target rate of 130 per million.



Within England, there is wide variation in implant rates between Networks. For ICDs, the highest rate of implant is 131 per million in the North East London Cardiac and Stroke Network, the lowest 34 in Herefordshire and Worcestershire Cardiac and Stroke Network. For CRT, the highest rate is 182 per million in the Birmingham, Sandwell and Solihull Cardiac and Stroke Network, the lowest 68 in the North Trent Network of Cardiac Care.

Within Networks, there is further wide disparity in implant rates for both devices between PCTs:



There is also significant variation in the ratio of CRT-P:CRT-D implants between Networks and in the ratio of ICD:CRT-D implants. In some Networks 2 CRT-P devices are implanted for every CRT-D device, whereas in others the ratio is the other way round with up to 4 CRT-D devices for every 1 CRT-P. Likewise, the ratio of ICD:CRT-D varies from 1:1 to 9:1. It is currently not known to what extent this reflects differences between patient populations as opposed to differences in clinical practice.

SUMMARY

ICD and CRT implant rates are low in the UK compared to the rest of Europe.

Within England, there is considerable variation in the implant rate for such devices between PCTs.

3. Applicable Service Standards

CORE STANDARDS

In Dec 2012, Heart Rhythm UK (HRUK) published “Standards for Implantation and Follow-Up of Cardiac Rhythm Management Devices in Adults – January 2013” (www.heartrhythmuk.org.uk). As the indications for CRT and ICD overlap significantly, it will be expected that centres implanting CRT devices would also be able to implant and follow-up ICDs. It will be expected that centres that implant CRT devices would implant both CRT-D and CRT-P devices. The HRUK recommendations include the following:

- There will be a minimum of 2 active implanting ICD/CRT consultant cardiologists per centre. Each implanter will have had appropriate training in ICD/CRT implantation as SpR/StR and retraining as a consultant if implantation has not been performed for ≥ 12 months. This will include familiarity with sub-muscular implant techniques and the use of subcutaneous arrays
- All implanters and physiologists will be fully competent in ICD/CRT follow-up
- All implanters and physiologists will undertake appropriate CPD in ICD/CRT therapy including implications for driving
- Each implanter will implant a minimum of 30 new complex device implants per year with a minimum total new device implant rate (including pacemakers) of 60 per year. If an operator is implanting CRT devices, at least 20 of these devices should be CRT-D/P and if an operator implants ICDs, at least 10 devices should be ICDs. Each centre will therefore perform a minimum of 60 new ICD or CRT implants per year, although 80 is desirable.
- For Specialist Registrar (SpR) training, consultant implanters will have implanted ≥ 30 new ICD and/or CRT implants / year for the previous 2 years (40 is desirable).
- Anaesthetic support will be available for ICD implantation
- Physiologists will have documented experience of at least 25 ICD implants and 25 CRT implants performed under supervision and experience of at least 25 ICD and 25 CRT follow-up evaluations. There will be a minimum of 2 cardiac physiologists actively involved in ICD/CRT implantation and follow-up in each centre. Each physiologist will be actively involved in a minimum of 35 new ICD/CRT implants per year.
- There must be a 24 hour service to deal with patients admitted with multiple shock delivery or other device related issues. This will consist of an appropriately

trained cardiac physiologist and an appropriately trained cardiologist either on site or with clearly defined, documented and agreed protocols with other implanting centres.

Lead Extraction

Lead extraction will be performed by two operators, at least one of whom must have undergone suitable training including 20 procedures under the direct supervision of an operator with an experience of >100 lead extractions. The procedures will normally be performed under general anaesthetic in a centre that has immediate access to cardiothoracic surgery. Not all ICD/CRT implanting centres will be expected to provide a lead extraction service.

RECOMMENDED STANDARDS

In practice all the Core Standards must be met. Further details of the Standards can be obtained from Heart Rhythm UK (www.heartrhythmuk.org.uk)

3.1 Applicable national standards e.g. NICE, Royal College

For ICDs:

- Technology Appraisal 95 (TA) – Implantable Cardioverter Defibrillators for Arrhythmias (<http://www.nice.org.uk/nicemedia/live/11566/33167/33167.pdf>)
- AHA/ACC/HRS Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities *Circulation* 2008; 117: 2820-40.

For cardiac resynchronisation therapy (CRT):

- TA120 – Cardiac resynchronisation therapy for the treatment of heart failure <http://www.nice.org.uk/nicemedia/live/11616/33962/33962.pdf>
- The European Society of Cardiology Guidelines for cardiac pacing and cardiac resynchronisation therapy *Eur Heart J* 2007; 28: 2256-95
- The European Society of Cardiology (ESC) 2010 focused update of ESC guidelines on device therapy in heart failure *Eur Heart J* 2010; 31: 2677-87
- The European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure *Eur Heart J* 2012; 33: 1787-847

Heart Rhythm UK Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults (2013) www.heartrhythmuk.org.uk

4. Key Service Outcomes

Device therapy is subject to immediate and long-term complications. There are also frequent advice and safety notices from manufacturers and MHRA (<http://www.mhra.gov.uk/index.htm>) which necessitate timely action.

All implanting centres must collect data on their patients, devices and follow-up which is immediately available and facilitates audit.

All implanting centres must contribute accurate and timely implant, follow-up, and complication data electronically to the National Cardiac Rhythm Management Audit (<http://www.ucl.ac.uk/>). This is a national quality requirement and is audited by the Care Quality Commission.

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