Heart Rhythm UK

Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices

HRUK, February 2011

1) Introduction

The purpose of this document is to facilitate the safe delivery of high-quality, evidence-based cardiac device therapy to all patients who may benefit.

This includes identification of patients with device indications, implantation of appropriate devices, patient and device follow-up, and data collection, storage and submission.

It includes the best available evidence and expert opinion on current practice and is in accordance with Chapter 8 of the National Service Framework for Coronary Heart Disease [1].

The source material for this evidence is listed in the Reference section and will be up-dated when new evidence is published.

It should be recognised that competency can only be defined effectively in terms of patient outcome; numbers given in this document are simply indicative and cannot be taken in isolation as evidence of competency or the ability to provide a safe, high-quality service.

This document is not intended to disrupt or disenfranchise existing, successful device services; it should be regarded as a template for developing best practise when starting *de novo* and a recommendation to enable successful but inadequately-resourced services to develop.

2) Definitions

The following definitions are used within this document.

For the purposes of this document, as some Trusts are spread across multiple sites, an implanting "Centre" is taken to mean a single hospital site where cardiac devices are implanted. It is accepted that operators may work at more than one Centre but all Centres should conform to the standards within this document.

The cardiac rhythm management (CRM) devices within the scope of this document include:

- Permanent pacemakers (PPM) implanted for bradycardia indications
- Cardiac resynchronisation therapy (CRT) devices, also known as bi-ventricular pacemakers, (CRT-P), and bi-ventricular defibrillators, (CRT-D).
- Implantable cardioverter defibrillators (ICDs) implanted for tachycardia ± bradycardia indications (but not heart failure, CRT-D)
- Implantable loop recorders (ILR)

3) Treatment indications

CRM devices are effective at improving quality of life and in reducing mortality. Their use is supported by the National Service Framework for Coronary Heart Disease chapter 8 [1], NICE [2, 3, 4] and international [5, 6, 7] guidelines. Although the implantation rates across the UK [Fig 1] have increased significantly over the past 10 years they remain below the European average [Fig 2] [8] and targets set by NICE [3]. There are also marked differences in implant rates across the UK [4] [9]. These disparities remain unexplained.

It is recognised that published guidance does not cover all patient groups and may not be appropriate in certain situations. Furthermore, clinical judgement based on published evidence must be used for indications not yet considered by NICE. However, it is important to demonstrate compliance with best practice and regular audit of device indications and outcomes is strongly recommended.

Where there is clinical uncertainty, discussion with an experienced colleague is recommended.

Previous national and network reports [8, 9] have criticised some pacing centres for apparent failure to comply with NICE guidance TA88 on pacing mode for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block [4]. It is essential that all implanting centres ensure accurate and timely implant data submission to the national database and that their practice is consistent with NICE guidance.

4) Requirements for performing pacemaker implantation

Safe device implantation requires appropriate environment, equipment and trained personnel. This section contains information on these areas. Centres fulfilling the requirements for pacemaker implantation will also fulfil the requirements for the implantation of ECG loop recorders.

a. Cardiologists

- There should be at least 2 active implanting consultants per centre [10]
- Each implanter should have had appropriate training in pacemaker implantation as a SpR/StR [11], and retraining as a consultant if implantation has not been performed for ≥ 12 months [10]
- At least 1 implanter should have accreditation in device therapy (HRUK or IBHRE)
- All implanters must be fully competent in pacemaker follow-up [12]

- All implanters must undertake appropriate CPD in device therapy [12] including implications for driving [13]
- Each implanter should perform ≥ 35 primary pacemaker implants / year [12]
- Each centre should therefore perform ≥ 70 primary pacemaker implants / year [10,12]
- SpR/StR training requires ≥ 25 primary pacemaker implants / year [11], so centres training an SpR/StR should perform ≥ 95 primary pacemaker implants / year
- All implanters must audit their personal complications and share these in an anonymised form within their centre and through CCAD for clinical governance purposes. If an implanter's complications were to exceed accepted limits (published complication rates are shown [14, table 1]) practice should be reviewed and advice sought from within the centre or elsewhere within the UK. Operators implanting fewer then 50 pacemakers / year may need to average their figures over 2 or more years to account for random variation.

b. Centres

- Implantation should be performed in a theatre appropriate for sterile procedures [10] and all aspects of the procedure
- All equipment for implantation and possible complications must be immediately available including external defibrillation [10]
- Appropriately trained cardiac physiologists, nurses, radiographers should be present [10]
- Each centre should maintain a database of device activity to allow immediate tracing of patients with device advisories and timely electronic submission of data to CCAD [10]
- Each centre must maintain a database of complications to facilitate clinical governance including:
    - pneumothorax requiring intercostal drain
    - pneumothorax not requiring intercostal drain
    - re-intervention within 12 months for:
        i. lead displacement
        ii. lead connection problem
        iii. lead failure
        iv. wound haematoma
        v. wound infection
        vi. wound pain
        vii. other reasons

c. Physiologists

- There should be at least 2 cardiac physiologists actively involved in pacemaker implantation and follow-up in each centre [10]
- Each physiologist should have had appropriate training in pacemaker implantation and follow-up [10]
- At least 1 physiologist should have accreditation in device therapy (HRUK or IBHRE)
- All physiologists must undertake appropriate CPD in device therapy and associated patient advice [12] including implications for driving according to DVLA guidelines (e.g. time post-implant, relationship to device therapies, impact of cardiac function etc)[13]
- Each physiologist should be actively involved in ≥ 35 primary pacemaker implants / year [12]

d. Nurses

- Implanting centres are expected to develop the role of Cardiac Arrhythmia Nurses as part of the CRM team at an appropriate (and sustainable) level as recommended in NSF Chapter 8 [1]

- Arrangements should be made that at least 2 nurses are denoted as specialist arrhythmia nurses/centre. This is important to allow continuity of care during periods of absence and can be achieved if necessary by nurses taking up dual or part time roles.
- Cardiac arrhythmia nurses should receive training appropriate to their involvement in the CRM team and should work according to protocols developed within their implanting centre
- Cardiac arrhythmia nurses involved in device management should have accreditation in device therapy (HRUK or IBHRE)
- Cardiac arrhythmia nurses must undertake appropriate CPD in device therapy and associated patient advice [12] including implications for driving according to DVLA guidelines (e.g. time post-implant, relationship to device therapies, impact of cardiac function etc)[13]

5) Additional requirements for performing ICD and/or CRT implantation

The implantation of ICDs and CRT carry higher immediate and long-term complication rates than do bradycardia pacemakers. As the indications for CRT and ICD overlap significantly, it would be expected that centres implanting ICDs should also be able to implant CRT-D devices.

- Each implanter should have had appropriate training in ICD/CRT implantation as SpR/StR [12], and retraining as a consultant if implantation has not been performed for ≥ 12 months [12]. This should include familiarity with sub-muscular implant techniques and the use of subcutaneous arrays.
- All implanters and physiologists must be fully competent in ICD/CRT follow-up [12]
- All implanters and physiologists must undertake appropriate CPD in ICD/CRT therapy [12] including implications for driving [13]
- Each implanter and physiologist should perform ≥ 10 primary ICD implants / year and/or ≥ 10 primary CRT implants / year [12]
- Each centre should therefore perform ≥ 20 primary ICD implants / year and/or ≥ 20 primary CRT implants / year [10, 12]
- For SpR/StR training, consultant implanters must have implanted ≥ 25 ICD and/or CRT implants / year for the previous 2 years [12]
- Immediate anaesthetic support must be available for ICD implantation
- Physiologists should 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.
- In order to assess patients for ICD/CRT therapy, centres must have access to
    - echocardiography for accurate ejection fraction and dyssynchrony
    - angiography
    - cardiac MRI
    - electrophysiology studies
    - revascularisation before (CABG) or after (PCR) 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≤30%, QRS>120ms) should represent approximately 20% of implants (on current estimates). To achieve an effective implant ratse of ≥ 20 ICD and CRT devices each year with a target implant rate of 100/million/year [10] would require a minimum population of 1,000,000 per implant centre.
- It should be recognised that competency can only be defined effectively in terms of patient outcome; numbers given in this document are simply indicative and cannot be taken in isolation as evidence of competency or the ability to provide a safe, high-quality service.

6) Requirements for lead extraction

Lead extraction involves the complete removal of a pacemaker or ICD lead with specialised tools not normally used for implantation [15]. The current indications for lead extraction are detailed in the 2009 Heart Rhythm Society Expert Consensus [15]. A draft HRUK document from 2005 also addressed these issues [Appendix a].

Device infection almost inevitably involves the leads will usually require removal of the complete system. After the first few months of implantation, it is impossible to predict whether leads can be removed safely with simple traction. Early discussion and/or referral to an extraction centre is strongly advised for suspected device-related infection.

Lead extraction should 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 [15]. The procedures should normally be performed under general anaesthetic in a centre that has immediate access to cardiothoracic surgery [15].

Centres should maintain a database of extraction procedures, indications and complications for clinical governance.

7) Implantable device follow-up standards

Device implantation is only the start of treatment. Patients with cardiac rhythm management devices require life-long follow-up with specialised medical and technical expertise and equipment. This should be performed in accordance with published "Guidelines for follow-up of implantable cardiac devices for cardiac rhythm management, HRUK October 2008 [17]. Consultants must have full understanding and active involvement with follow-up and programming/re-programming of devices; this must include a responsibility to teaching junior doctors, physiologists and nurses. SpRs/StRs must achieve competency in device follow-up as part of their specialist training.

Arrangements for 24-hour cover should be in place for all device patients. This is particularly important for ICD patients where device-related and arrhythmic complications occur frequently and can be life-threatening.

Follow-up should be performed at nationally accepted intervals (within 2 months of implantation and then 6-12 monthly for bradycardia pacing and 3-6 monthly for CRT and ICD therapy). Remote monitoring of devices should be encouraged. Patients should have urgent follow up if they report symptoms which may be associated with their device.

In-clinic follow-up should 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 and submitted to CCAD (where appropriate)
- Psychological support and early identification of distress
- Communication with cardiologists, heart failure team and general practitioners as indicated
- Given the complexity of high-voltage devices and the potential for patient risk in the event of malfunction, remote monitoring should be considered the standard of care in the UK and should be available to all services providing ICD/CRT-D follow-up.

End of Patient Life Management:

- Device implantation centres are strongly encouraged to follow a local policy for the management of end of patient life.
- Device therapy termination should be a consensus between the device consultant, 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.

8) Audit

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 data electronically to the National Pacemaker & ICD Database (http://www.ic.nhs.uk/services/national-clinical-audit-support-programme-ncasp/heart-disease/cardiac-rhythm-management). This is a national quality requirement and is audited by the Care Quality Commission.

- Data from all local centres on indications for implantation, early and late complications should be presented annually at Network arrhythmia group meetings

- The number of patients receiving single chamber ventricular pacemakers when in sinus rhythm should be recorded and the reason for this mode of pacing and the physician making the decision must be recorded each case. Centres implanting ≥ 10% of patients in sinus rhythm with VVI(R) devices should review their practice in accordance with NICE guidance [10].

9) Figures

www.devicesurvey.com

Fig 1 - National

PPM **ICD** **CRT**

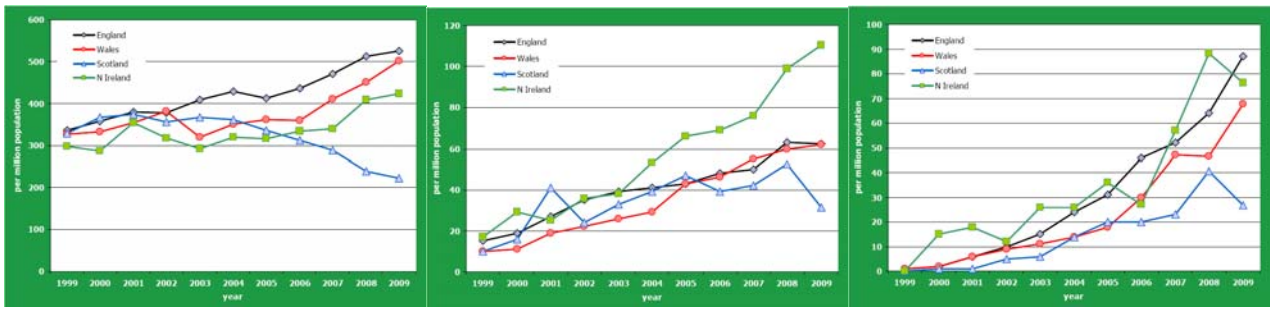
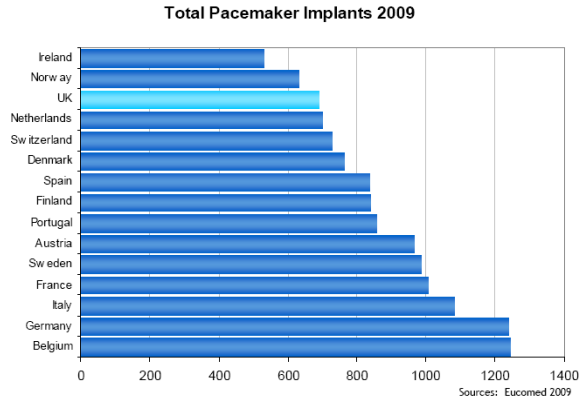
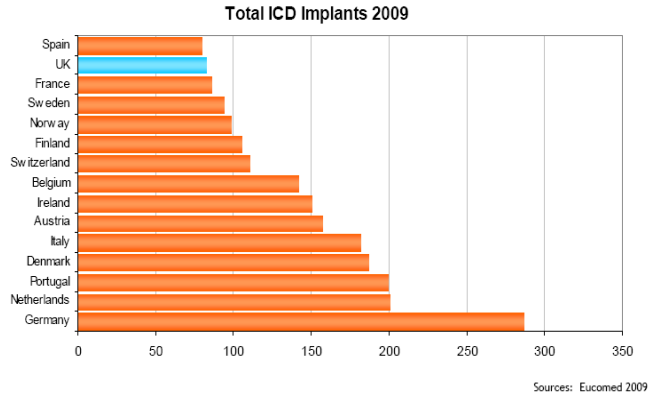


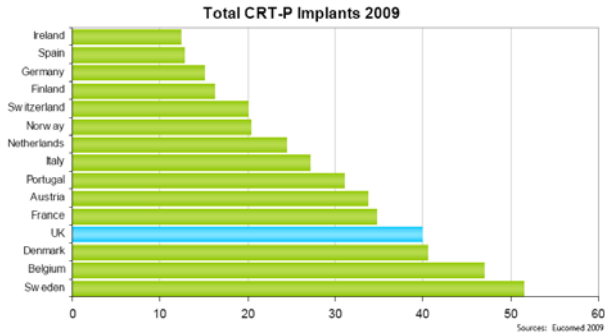
Fig 2 – International

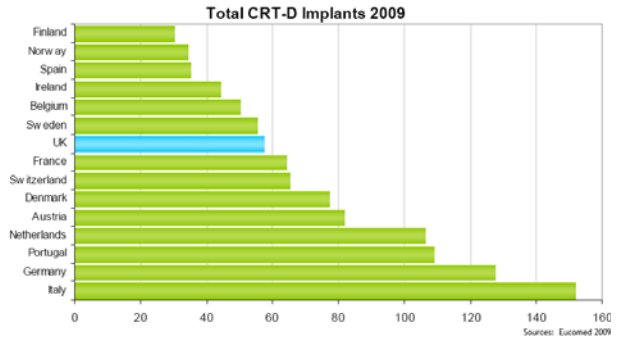
PPM **ICD**



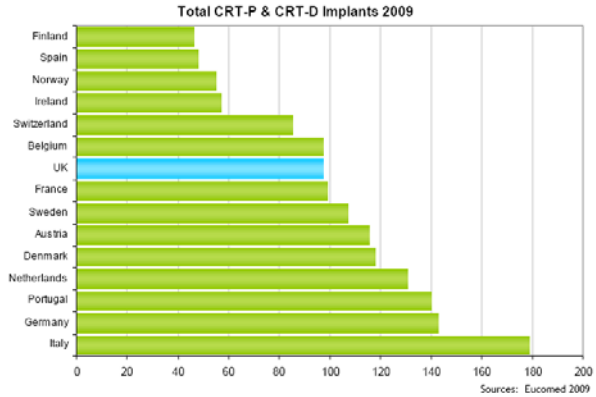


CRT





CRT and ICD



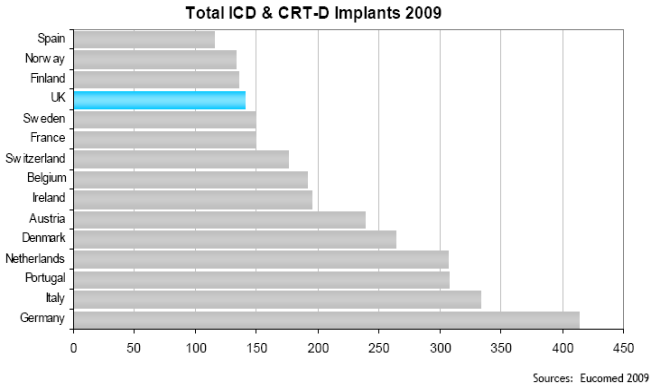


Fig 3 - National

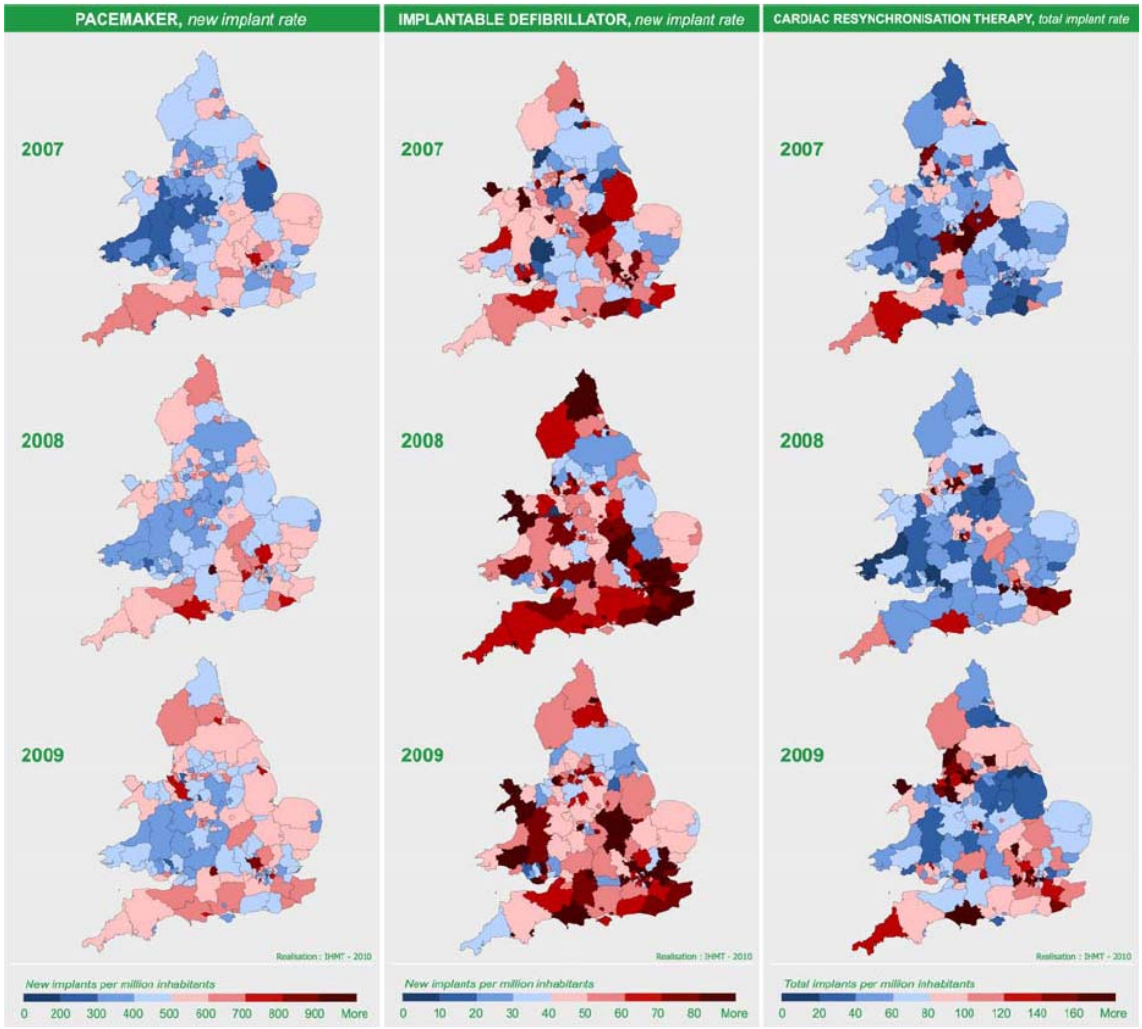


Table [1]

Complications rates for pacemaker implantation, adapted from [14]:

Study	Ventricular lead displacement	Atrial lead displacement	Pneumothorax	Perforation	Infection
MOST n=2010	0.7%	1.7%	1.5%	0.3%	0.2%
Chauhan n=286	1.4%	3.8%	0.7%	n/a	1.3%
Aggarwal n=587	0.5%	1.6%	0.8%	n/a	1.0%
Kiviniemi n=446	2.0%	4.4%	0.7%	0.7%	1.8%
Link n=407	1.7%	0.5%	2.0%	1.0%	0.25%
weighted mean	**1.0%**	**2.0%**	**1.3%**	**0.4%**	**0.6%**

We thank Colleagues from the North East Cardiovascular Network for kind permission to utilise and modify their original document. *HRUK Council, June 2010*.

10) Reference documents
(all freely available on-line through the links provided unless otherwise stated)

1) National Service Framework for Coronary Heart Disease; Chapter 8

2) Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. NICE TA 88, 2005

3) Implantable cardioverter defibrillators (ICDs) for the treatment of arrhythmias (review of TA11) NICE TA 95, 2006

4) TA120 Heart failure - cardiac resynchronisation: guidance
NICE 23 May 2007

5) Guidelines for cardiac pacing and cardiac resynchronization therapy
European Heart Journal 2007 28(18):2256-2295

6) ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities
J Am Coll Cardiol, 2008; 51:1-62

7) ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death
J Am Coll Cardiol, 2006; 48:247-346

8) Heart rhythm devices: UK national survey 2007

9) NECVN review of pacemaker and ICD implantation in 2007

10) Clinical competence in electrophysiological techniques
Heart 1997;**78**:403-412

11) Cardiology Specialty Training Curriculum May 2007
JRCPTB May 2007

12) HRS training pathways for implantation of ICDs and CRT devices
Heart Rhythm 2004;**3**:371-375

13) At a glance guide to the current medical standards of fitness to drive
DVLA 07/07/09

14) Complications arising after implantation of DDD pacemakers: the MOST experience
The American Journal of Cardiology 2003;92:740-741 (not freely available on-line)

15) Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management
Heart Rhythm 2009; 6:1085-1104

16) Standards of good practice for cardiac implantable devices: Lead extraction
Draft document for discussion at HRUK Council, July 2005 (appendix 1)

17) Clinical guidance by consensus for the follow-up of implantable cardiac devices for cardiac rhythm management
HRUK October 2008

18) Heart Rhythm Device National Survey 2009. www.devicesurvey.com

11) Appendix a:

STANDARDS OF GOOD PRACTICE FOR CARDIAC IMPLANTABLE DEVICES: LEAD EXTRACTION

A discussion document, approved by HRUK Council, July 2005

Introduction:

Clinical governance demands that all clinical practice shall be delivered at a standard defined by peer-group review; it is therefore appropriate for Heart Rhythm UK (HRUK, formally the British Pacing and Electrophysiology Group), on behalf of the British Cardiac Society (BCS) to assist in this process by defining expected standards of clinical practice in extraction of pacemaker and ICD leads in the United Kingdom.

This document examines the processes involved in delivering an effective lead extraction service in the first decade of the 21st century and will define minimum standards to be expected in the settings in which care of the patient requiring lead extraction is delivered.

It must be recognised that cardiac pacing and ICD implantation in the UK take place in a wide variety of settings and staffing situations; whilst this should not influence expected standards, it will influence recommendations for expectation of availability of lead extraction services in different hospitals.

Lead Extraction is defined according to the NASPE Policy Statement: [1]
1. Removal of a lead with the assistance of specialized equipment regardless of the implant duration. This may include but is not limited to the use of specialized stylets that are not included as part of the typical implant package, sheaths with or without additional cutting capability (e.g., metal composition, laser, and radiofrequency current), snares, grasping devices, or other devices used to engage or entrap and remove the lead or lead fragments.
2. Removal of a lead from a route other than via the implant vein.
3. Removal of any lead that has been implanted for more than one year.

Facilities and location:

Lead removal/extraction/revision required within a short period of implantation can usually be managed without problems by the implanting clinician/centre. The time period during which simple revision can be undertaken will vary according to the type of lead, but is likely to be around 4-6 months post-implant. Thereafter, or where there is doubt about ease of revision/removal, referral to a centre with specific lead extraction experience and facilities should be considered.
The ideal facility for lead extraction is an operating theatre with emergency availability of general anaesthesia and support from a cardiothoracic surgical team able to deal with cardiac/vascular perforation/tears. A dedicated pacing laboratory in which the highest standards of sterility can be maintained may be suitable if the above anaesthetic/surgical support is available. Details of the relevant equipment required have also been provided [1] and must include resuscitation equipment and drugs to provide Advanced Life Support (ALS), along with staff trained and validated to deliver ALS.
Good quality C-arm fluoroscopy must be available, with image storing/video facilities and the ability to acquire contrast-enhanced images. Operating/imaging tables must allow vascular access to the patient from both sides and from femoral and subclavian/cephalic approaches.
Equipment required for extraction should include at least two of the following:

1. Sheath extraction (including femoral work station/snares etc)
2. Electro-cautery
3. Laser

Centres providing pacemaker lead extraction should have rapid access to urgent cardiac surgical support (within 30 minutes) and undertake a minimum of 20 procedures per year.[1] Lead extraction will usually be undertaken in tertiary cardiac centres, but there may be historical and geographical reasons for a service to be established in a secondary centre with adequate/appropriate facilities, staffing, experience and surgical support.

Staffing and Training:

Centres offering lead extraction should have at least 2 cardiologists implanting high volumes of pacemakers/ICDs (minimum 200/year for centre) of whom at least one is trained/experienced in lead extraction. This training must include the assessment and risk stratification/triage of the patient, in addition to the extraction procedure itself. The procedure should be undertaken by 2 cardiologists; these may be 2 consultants, 1 consultant plus trained staff grade or one consultant recognised for extraction training plus an SpR experienced in pacing/ICD implantation (i.e. has completed basic requirements for pacing/ICD implantation). It should also be recognised that other clinicians, e.g. interventional radiologists, cardiac/thoracic/vascular surgeons, may have appropriate skills to contribute to the lead extraction team, and that paediatric colleagues will need to be involved in a comprehensive tertiary service. The team must also have experience with multiple vascular approaches required, e.g. subclavian, femoral etc.
A centre would be expected to undertake a minimum of 20 extraction procedures per year; activity of less than 12 per year for 2 consecutive years would require re-training of consultant staff.

All lead extraction centres must be prepared to provide training for specialist EP/device SpRs attached to their Regional Training Rotation; where no centre exists within the Region, it may be necessary to provide training for other Regions.

Continuing Professional Development:

Lead extraction practice and requirements are changing continuously; in addition to the technological developments that bring new facilities to permanent pacemakers and ICDs, the lead sites and approaches are being extended on a regular basis. These changes require an understanding that can only be brought about through continuing education. This education may be provided in association with the pacemaker/ICD industry where it relates to the devices or through contact with other centres and attendance at meetings of Professional Societies (National and International). A commitment to continuing education is required to maintain a satisfactory lead extraction service and Trusts must recognise the need to support and monitor similar educational processes for medical, technical and nursing staff.

Monitoring and audit of activity

Benchmarks:
Maintenance of standards in clinical practice requires the establishment of benchmarks against which the service can be measured. These benchmarks may be affected by the setting in which the practice takes place, but for most aspects of lead extraction there will be standards which will be expected regardless of setting.
The benchmark for lead extraction is likely to be mortality but assessments will include:

1. Lead extraction success rate
2. Rate of other complications (pneumothorax, haematoma, re-operation)
3. Average length of stay
4. Waiting times between referral, assessment and implantation
5. Mortality versus National/International evidence base

All centres undertaking lead extraction must have robust mechanisms in place to capture and audit all activity and potential complications; these should be audited at least annually and action taken if activity or complications are significantly different from national averages. HRUK maintains a national database of certain aspects of pacemaker/ICD activity; it is vital that all centres make comprehensive annual returns as these data allow for central monitoring and audit of national practice, in addition to providing predictive data for planning future needs.

References:

1. Love CJ, Wilkoff BL, Byrd CL *et al*. **NASPE Policy Statement**: Recommendations for extraction of chronically implanted transvenous pacing and defibrillator leads: indications, facilities, training. North American Society of Pacing and Electrophysiology Lead Extraction Conference Faculty. Pacing Clin Electrophysiol. 2000;23:544-51.