Quality Standards for the Implantation of Cardiac Rhythm Management Devices

Pan-London Arrhythmia Project Group

Version 3 (18th July 2011)

Standards for Implantation of Permanent Pacemakers (including Implantable Loop Recorders)			
No.	Item	Quality Standard	Evidence
1.	**Implanting Centres**	There should be at least 2 active implanting consultants per centre. Each implanting centre must have a lead consultant responsible for device therapy.	Departmental Team Structure HRUK[1]
		Each centre must perform at least 70 pacemaker implants per year. If Specialist Registrars are training in a centre, the centre should be performing at least 25 additional implants per SpR per year.	CCAD HRUK[1]
		Implantations must be performed in an operating theatre/dedicated pacing laboratory/cardiac catheter laboratory appropriate for sterile procedures and equipped for all aspects of the procedure.	
		All necessary equipment for implantation and possible complications must be immediately available including appropriate fluoroscopic imaging, echocardiography, equipment for pericardiocentesis and external defibrillation.	
		Staffing in each implanting centre must include: • Appropriately trained and experienced consultant cardiologists (see point 2); • Nurses with experience in pacemaker implantation including specific experience of the care of the sedated patient (see point 4); • Senior cardiac physiologists experienced in pacemaker implantation, testing, programming and troubleshooting of cardiac devices (see point 3); • Radiographers appropriately trained in fluoroscopy and with experience of cardiac procedures	Departmental Team Structure
		Each centre must have procedures in place to care for patients presenting at any time with complications or device faults/failed therapies following implantation.	Emergency Care Pathway
		The centre must maintain a database of device activity	

		All implanting centres must collect data on their patients, devices and follow-up which is immediately available and facilitates audit and to allow immediate tracing of patients affected by device alerts and advice from manufacturers/the MHRA and to provide for timely electronic submission of data to CCAD. 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-auditsupport-programme-ncasp/heart-disease/cardiac-rhythm-management). 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.	HRUK[1]
		The centre must maintain a database of complications to facilitate clinical governance including the following categories currently stipulated by the Devices Survey/CCAD: 1. Pneumothorax (whether or not requiring aspiration/drainage) 4. Haematoma requiring evacuation 6. Tamponade 7. Lead displacement requiring reposition 7A. Lead displacement (right atrium) requiring reposition 7R. Lead displacement (right ventricle) requiring reposition 7L. Lead displacement (left ventricle) requiring reposition 8. Haemothorax 9. Pericardial effusion 10. Wound revision (Any of the above occurring within 3 months of implantation)	
No.	Item	Quality Standard	Evidence
2.	**Consultant Cardiologists**	Consultant Cardiologists carrying out implantations must be able to demonstrate that they have undergone formal training in pacemaker implantation and have carried out at least 100 such implantations during their training.	Certified for competency in pacing

		At least 1 implanter should have accreditation in device therapy (HRUK or IBHRE).	Accreditation from HRUK or IBHRE
		Any Consultant who has not been undertaking implants in the preceding 12 months should undergo appropriate retraining.	
		Each consultant/implanter performing implants must perform or supervise at least 35 pacemakers per year.	CCAD HRUK[1]
		Each consultant/implanter performing implants must personally audit their complication rates on an annual basis. These data are to be shared through CCAD for clinical governance purposes. Audited complications are also to be shared in an anonymised form within the centre and with the local Cardiac and Stroke Network. Practice should be reviewed and advice sought if an implanter's complications exceed accepted limits.	CCAD
		Each consultant/implanter must maintain ongoing relevant CME/ CPD in device therapy including DVLA[2] and CAA guidelines.	Annual local appraisal
		All implanters should be fully competent in pacemaker follow-up and troubleshooting.	
No.	Item	Quality Standard	Evidence
3.	**Cardiac Physiologists**	Each implanting centre must have at least two cardiac physiologists trained and actively involved in pacemaker implantation and follow-up	Departmental team structure HRUK[1]
		Each physiologist should be actively involved in at least 35 primary pacemaker implants per year.	Log Book HRUK[1]
		At least 1 physiologist should have accreditation in device therapy (HRUK or IBHRE).	Certificate (if already qualified) or Log Book (if working towards it)
		Each cardiac physiologist must perform a minimum of 100 pacemaker follow-ups per year.	Log Book HRUK[3]

		All cardiac physiologists must undertake regular and ongoing CPD in device therapy and be aware of the likely implications for patients in certain occupations (such as drivers, pilots etc.)	Annual local appraisal
No.	Item	Quality Standard	Evidence
4.	**Nurses**	At least 2 nurses per centre should be designated as specialist arrhythmia nurses.	HRUK[1]
		Cardiac arrhythmia nurses should receive training appropriate to their involvement in the CRM team.	
		Cardiac arrhythmia nurses should work according to local and national protocols as agreed by the centre within which they work.	
		Cardiac arrhythmia nurses involved in device management should have accreditation in device therapy (HRUK or IBHRE).	Accreditation from HRUK or IBHRE
		Cardiac arrhythmia nurses should undertake appropriate CPD in device therapy particularly directed toward equipping them with the skills and knowledge in order to provide patients with information and advice according to their needs (including implications for driving and other occupations).	
		Each cardiac arrhythmia nurse should have a clearly defined role as part of the device management team but should not be expected to undertake those duties performed by cardiac physiologists.	
Additional Standards for Implantation of Complex (CRT and ICD) Devices			
No.	Item	Quality Standard	Evidence
5.	**Implanting Centres and Cardiologists**	Centres implanting complex devices must have at least 2 consultant cardiologists who are trained in the implantation and follow-up of complex devices and who are available to treat patients. Device therapy should have been a substantial part of their training, which must have included competence with all means of vascular access, techniques of sub-muscular implant and some experience with subcutaneous arrays. District General Hospitals (DGHs) implanting complex devices should have their own on-site consultant trained in implantation and management of complex devices. The majority of DGHs are unlikely to have two	Network Membership HRUK[1]

		Devices Consultants and there must be in place a formal link to one or more named Devices Consultant(s) via their Network to allow for cover and cross-site working. There should be a clear referral pathway for staff to obtain advice in the absence of the DGH Device Consultant. Job planning to allow cross-site working in both directions should be encouraged. Consultants wishing to implant complex devices who have not undergone appropriate training at Registrar/SpR level should fulfil the minimum criteria for implanting standard pacemakers and undergo formal training and appraisal with an accredited Devices consultant before implanting complex devices. Each consultant must demonstrate appropriate training in troubleshooting and follow-up of ICD and CRT devices. Each implanting consultant must undertake dedicated, appropriate CME/CPD in ICD/CRT therapy and this should include familiarity with guidance from agencies which may be relevant to certain occupations and activities undertaken by patients and especially those guidelines issued by the DVLA[2].	Local Clinical Governance
	Number of Complex Device Implants	Each implanter should perform or supervise at least 10 CRT implants / year and at least 10 primary ICD (+/- CRT) implants / year. Each centre should therefore perform ≥ 20 new ICD implants/year and/or ≥ 20 new CRT implants/year. In order to undertake SpR/StR training, consultant implanters must have implanted or supervised ≥ 25 ICD and/or CRT implants per year for the previous 2 years.	HRUK[1] HRUK[1]
	Cardiac Physiologists	Centres must have at least two cardiac physiologists trained in the implantation and follow-up of ICD and CRT devices. Physiologists training in complex device therapy should acquire documented experience of at least 25 ICD implants and 25 CRT implants performed under supervision and have experience of at least 25 ICD and 25 CRT follow-up evaluations. Each device physiologist should perform ≥ 10 primary ICD (+/- CRT) implants per year and ≥ 10 primary CRT implants per year.	Certificate of training Logbook HRUK[1] Logbook

		Each cardiac physiologist must carry out a minimum of 50 complex device (ICD and CRT) follow-ups per year. All physiologists should undertake appropriate CPD in ICD/CRT therapy and should be aware of the implications of ICD/CRT implants on certain occupations and activities such as driving (DVLA guidelines).	Logbook Logbook
	Anaesthetic Support	Immediate anaesthetic support should be available when requested for ICD implantation	HRUK[1]
	Assessment for Device Therapy	Centres must have in place mechanisms to perform thorough investigation of any patient potentially requiring a complex device. Where a centre does not have on site access to all the necessary services, there should be clearly defined links to a centre or centres that can provide: 1. echocardiography for accurate ejection fraction and assessment of dyssynchrony 2. cardiac catheterisation/angiography 3. cardiac MRI 4. electrophysiology studies 5. surgical or percutaneous revascularisation 6. anaesthetic support for sedation and general anaesthesia 7. services of a clinical geneticist	Care Pathway Care Pathway
	Pre-implant Counselling	Centres must have in place mechanisms whereby patients who are identified as suitable for a complex device can be counselled beforehand. Items that must be covered in this process include the impact that ICD implantation will have on their health and lifestyle and the risks and benefits of having a complex device implanted. Centres must schedule ICD/CRT implants in such a way that every patient has the opportunity to reflect upon the decision to have such a device fitted.	Care Pathway Patient Information
		The person or persons carrying out the counselling of patients prior to ICD/CRT implantation should have specific experience in pre-implantation counselling.	
	ICD Follow-Up	All patients that have had an ICD/CRT fitted must be offered follow-up in a clinic with physiologists fulfilling the criteria (Section 5) to perform complex device interrogation and troubleshooting and where there is a Devices Consultant available for support when necessary.	Protocol and clinic schedule

		Protocols should be in place for the emergency management of ICD patients receiving frequent/recurrent shocks. If 24 hour/7 days per week cover is not available from a devices physiologist onsite then plans should be in place for emergency cover within the network and those plans made known to the A&E department(s) and the physicians in charge of the Emergency Admissions Unit(s) of that centre.	Care Pathways
		All patients should be made aware of local ICD Support Groups. Where these are not available, centres must support the development of such a group for their patients.	Patient Information
		Please refer to section 7 for additional guidelines for post-discharge follow up.	
No.	Item	Quality Standard	Evidence
Box Changes and Lead Extractions			
No.	Item	Quality Standard	Evidence
6.	**Centres for lead extraction.**	Lead extraction should only be performed in a centre with appropriately trained operators with all appropriate equipment readily available and with ***onsite,*** surgical cover available immediately if necessary. Guidelines for lead extraction are outlined in the Heart Rhythm Society Expert Consensus statement (2009)[4] and HRUK (2005)[5]. 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 in lead extraction. Training would involve performing 20 procedures under the direct supervision of an operator with an experience of >100 lead extractions. The procedures should normally be performed under general anaesthetic in a centre that has immediate access to cardiothoracic surgery. Centres should maintain a database of extraction procedures, indications and complications for clinical governance	Care pathway
		Centres performing box changes in devices that have been implanted in a sub-pectoral position must have	Care pathway

		access to general anaesthetic support.	
Post Discharge			
No.	Item	Quality Standard	Evidence
7.	**Follow-up**	Follow up must be performed in accordance with published "Guidelines for follow-up of implantable cardiac devices for cardiac rhythm management, HRUK October 2008[3].	CCAD HRUK[3]
		Consultants must have full understanding of and be actively involved with follow-up and the programming/re-programming of devices; this includes a responsibility to teaching junior doctors, physiologists and nurses	
		SpRs/StRs should achieve competency in device follow-up as part of their specialist training.	
		Arrangements must be in place to provide 24-hour cover for all patients with complex devices (especially those with a defibrillator function).	Network
		Follow-up must be performed at nationally accepted intervals: 1. Within 2 months of implantation; 2. then 6-12 monthly for bradycardia pacing 3. 3-6 months for CRT and ICD therapy or otherwise as dictated by the findings via remote monitoring system(s)	

		In-clinic follow up should include: 1. Review of site of implant 2. Analysis of rhythm data recorded by device (including atrial fibrillation or ventricular arrhythmias which may require input from a physician) 3. Device checks – battery status, lead impedance, pacing thresholds, sensitivity 4. Access to specialised echocardiography services when required to optimise CRT function 5. Referral to specialised electrophysiology services when necessary for the management of atrial and ventricular arrhythmias 6. Data recording in a form which can be transferred to another centre and submitted to CCAD (where appropriate) 7. Psychological support and early identification of distress 8. Communication with cardiologists, heart failure team and general practitioners as indicated. Given the complexity of high-voltage devices and the potential for risk to the patient 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.	HRUK[1] HRUK[3]
		Patients should be considered for referral for cardiac rehabilitation in line with the Department of Health's Cardiac Rehabilitation Commissioning Pack.	Department of Health[13]
8.	**Minimum Data Set (MDS)**	The MDS must include the following: • Lead displacement rate • Implant- related infection rate • Rate of other complications (pneumothorax, haematoma, re-operation etc as specified by Devices Survey/CCAD-see section 1) • Length of stay • Implant rate per million population • Indication and criteria for implantation of pacemakers and complex devices [6,7,8,9] • Screening time and X-ray dosage	CCAD; ACC/AHA/HRS 2008 Guidelines[6] NICE Guidance[7,8] ESC Guidelines[9]

Clinical Research			
No.	Item	Quality Standard	Evidence
9.	**Implanting Centres**	CRM implanting centres should encourage their clinicians to participate in research programmes as these often bring a variety of benefits to both patients and implanting centres alike.	Research proposals submitted each year
		Research programmes must be agreed by the Local Research and Ethics Committee (LREC) and meet guidance from the Research Governance Framework for Health and Social Care.	LREC approval
Management of patients nearing end of life			
No.	Item	Quality Standard	Evidence
10.	End of life patient management	Every centre looking after patients with ICDs should have a local policy for the management of patients reaching end of their life that includes an ICD de-activation policy. The potential scenarios for ICD de-activation should be discussed at the pre-implantation counselling. Guidance is available via the British Heart Foundation (2008)[10] and EHRA Expert Consensus Statement (2010)[11]. See also: http://www.nclcn.org.uk/images/stories/heartfailureguidelines/ICDconsensusdocumentfinalnov08..pdf This consensus document from the North Central London Cardiac & Stroke Network[12] includes the relevant aspects of the Mental Capacity Act and provides algorithms for the deactivation of devices in the competent patient and in the case of a patient who lacks capacity.	Local Policy Document BHF[10] EHRA[11]

The Patient Perspective			
No.	Item	Quality Standard	Evidence
11.		Patients should be treated in line with the NHS Constitution and guidelines outlined by Commissioning Support for London.	nhs.uk[14] csl.nhs.uk[15]

References:

1. Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices, HRUK, February 2011.

http://www.hruk.org.uk/html/main/guidelines.html

2. At a glance guide to the current medical standards of fitness to drive. DVLA February 2011.

http://www.dft.gov.uk/dvla/medical/ataglance.aspx

3. Clinical guidance by consensus for the follow-up of implantable cardiac devices for cardiac rhythm management

HRUK October 2008 http://www.hruk.org.uk/html/main/guidelines.html

4. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

Heart Rhythm 2009; 6:1085-1104

http://www.hrsonline.org/ClinicalGuidance/#crm

5. Standards of good practice for cardiac implantable devices: Lead extraction. Draft document for discussion at HRUK Council, July 2005.

http://www.hruk.org.uk/html/main/guidelines.html

6. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities. Heart Rhythm. 2008 Jun;5(6):e1-62.
http://www.hrsonline.org/ClinicalGuidance/#crm

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

8. TA120 Heart failure - cardiac resynchronisation: guidance NICE 23 May 2007.

9. 2010 Focused Update of ESC Guidelines on device therapy in heart failure: an update of the 2008 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC Guidelines for cardiac and resynchronization therapy. Europace. 2010 Nov;12(11):1526-36.

http://www.escardio.org/guidelines

10. Implantable Cardioverter Defibrillators In Patients Who Are Reaching The End Of Life 2008. British Heart Foundation.

http://www.bsh.org.uk/portals/2/icd%20leaflet.pdf

11. EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal of therapy. Europace. 2010;12(10):1480-1489

12. Consensus document on the decision to deactivate Implantable Cardioverter Defibrillator (ICD) therapy in a terminally ill patient**.**

http://www.nclcn.org.uk/images/stories/heartfailureguidelines/ICDconsensusdocumentfinalnov08..pdf

13. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_117504

14. http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/EasyRead2010.pdf

15. http://www.csl.nhs.uk/Publications/Documents/The%20Patient%20Perspective%20-%20FINAL%20(CSL%20Version).pdf