



4th October 2011



Chris Plummer



standards

- ♥ history
- ♥ methodology
- ♥ HRUK adoption
- ♥ network effects
- ♥ future changes.



history

- ♥ network standards
- ♥ presentations 2nd February 2009
- ♥ commissioners – Yorkshire, NECVN
- ♥ document November 2009
- ♥ discussion at NECVN arrhythmia group
- ♥ adoption by HRUK February 2011
- ♥ Network CAG adoption
- ♥ benchmarking ...



methodology

statements of best practice

- ♥ establish national standards for device therapy
- ♥ on-going development of high-quality services
- ♥ standards for network approval of new centres
- ♥ inform Trusts of requirements for a devices service.



methodology

statements of best practice

- ♥ standards high to drive up quality
- ♥ not to shut down existing high-quality sites
- ♥ not to prevent development of new centres
- ♥ provide a framework for collaboration across networks
- ♥ benchmark to improve services.



methodology

best available published evidence / opinion

- 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



structure

- ♥ introductions / definitions
- ♥ treatment indications (NICE/ESC/HRS)
- ♥ standards for pacemaker implantation
 - ♥ cardiologists
 - ♥ centres
 - ♥ physiologists
 - ♥ nurses
- ♥ additional requirements for ICD/CRT implantation
- ♥ lead extraction
- ♥ device follow-up
- ♥ audit.



pacemaker implantation

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 than 50 pacemakers / year may need to average their figures over 2 or more years to account for random variation.

years to account for random variation

fewer than 50 pacemakers / year may need to average their figures over 2 or more years to account for random variation



pacemaker implantation

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



pacemaker implantation

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]



pacemaker implantation

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]



ICD / CRT implantation

- 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.



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.

clinical governance

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

clinical governance in a centre that has immediate access to cardiothoracic surgery [15]

follow-up

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 life management

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.



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 $\geq 10\%$ of patients in sinus rhythm with VVI(R) devices should review their practice in accordance with NICE guidance [10].

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

complications

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

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

weighted mean

1.0%

2.0%

1.3%

0.4%

0.6%

benchmarking

North of England Cardiac Rhythm Network		BENCHMARKING AGAINST THE HEART RHYTHM UK STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF CARDIAC RHYTH MANAGEMENT DEVICES										NHS North of England Cardiovascular Network											
Key		<ul style="list-style-type: none"> Green: Good practice (meets or exceeds standard) Yellow: Good practice (meets or exceeds standard) Orange: Good practice (meets or exceeds standard) Red: Good practice (meets or exceeds standard) Grey: Not reported 																					
Standard	Local Data	Cardiologists										Centres				Physicians				Nurses			
Standard	Local Data	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1. Are there at least 2 centres implanting permanent pacemakers into patients that appropriate timing in patients at risk (typically Negative gate (NPG)) or in waiting for a permanent pacemaker for not been performed for 12 months	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
2. Has at least 1 physician achieved accreditation in device therapy (EPIC or EPIC-E) An all-England study component is a separate follow up	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
3. Have all implanters achieved appropriate EPIC or device therapy (including implantations for driving	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
4. Does each implantor perform: 20 primary pacemakers or implants per year	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
5. Does the centre maintain a database of implantations for pacemakers per year	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
6. Does the centre maintain a database of implantations for pacemakers per year	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
7. Do all implanters in pacemakers with their personal complication	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
8. Are these complication rates in an implanted from within the centre and through CCAD for clinical governance purposes	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
9. If an implantor complication rate is raised accepted that it practice improved and advice sought with other centres or clinicians in the UK	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
10. Are all implantations performed in a centre appropriate for clinic procedures and all aspects of the procedure	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
11. Is all equipment for top up and/or adjustment completed in a timely and suitable manner (including remote adjustment)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
12. Are all appropriate training cardiac physiologists, nurses and radiologists present during the implantation	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
13. Does the centre maintain a database of device therapy (EPIC or EPIC-E) for all patients with device implanted and they are submitted to the CCAD	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
14. Does the centre maintain a database of complications to facilitate clinical governance including: <ul style="list-style-type: none"> • pacemaker or implantation related death • pacemaker not repairing external defibr • re-implantation within 1 month for • need for pacemaker • need for generator • need for lead • need for ventricular • need for ablation • need for pain • other requests 	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
15. Are there at least 2 cardiac physiologists actively involved in pacemaker implantations and follow up in the centre	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
16. Has each physiologist had appropriate training for pacemaker implantation and follow up	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
17. Has at least 1 physician achieved accreditation in device therapy (EPIC or EPIC-E) An all-England study component is a separate follow up	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
18. Have all implanters achieved appropriate EPIC or device therapy (including implantations for driving	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
19. Does each implantor perform: 20 primary pacemakers or implants per year	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
20. Does the centre maintain a database of implantations for pacemakers per year	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
21. Do the Centre All-England study included in their management team accreditation in device therapy (EPIC or EPIC-E)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
22. Have all Cardiac Rhythm Nurses achieved appropriate EPIC or device therapy (including implantations for driving	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%



network effects

- ♥ highlighted differences in practice / resources
- ♥ audit
 - ♥ implant numbers
 - ♥ national data submission
 - ♥ complication rates
- ♥ helped to establish criteria for a new centre.



future changes

- ♥ housekeeping
 - ♥ update
 - ♥ hyperlinks
- ♥ numbers
 - ♥ 35 PPMs, 10 CRT/ICD ?!
- ♥ box-changes
 - ♥ higher immediate and long-term complication rates – only performed by level 3 operators?!.



future changes

- ♥ consultants (re)training
 - ♥ as much experience as necessary to demonstrate competence = the same as StRs (6 x level 3 DOPS by two observers – preferably not the trainers)
- ♥ remote monitoring standards
 - ♥ capacity to make service more efficient
 - ♥ capacity to make service less efficient
 - ♥ would standards be helpful ?
 - ♥ what would the evidence base be ?.



future changes

- ♥ complications
 - ♥ definitions
 - ♥ methodology of collection
 - ♥ reporting
 - ♥ benchmarks
 - ♥ actions ?
 - ♥ consultants ≠ StRs
- ♥ other suggestions ?.



any questions

