



**STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF
CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS**
January 2015

1. INTRODUCTION

This document replaces the previous Heart Rhythm UK document "Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults" issued in 2013. It has been produced by a group of cardiac electrophysiologists with an interest in device therapy, cardiac physiologists and specialist arrhythmia nurses drawn from both tertiary centres and district general hospitals and approved by the Council of the British Heart Rhythm Society (BQRS) in December 2014. This document will be reviewed by BQRS on a bi-annual basis.

The purpose of the 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, data collection, storage and submission.

It includes the best available evidence and expert opinion on current practice. The source material for this evidence is listed in the References section.

It is recognised that competence can only be defined effectively in terms of patient outcome. Numbers given in this document are indicative and should not be taken in isolation as evidence of competence 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 practice when starting *de novo* and a recommendation to enable successful but inadequately resourced services to develop.

This document is not intended to replace Trust policies and other legislation e.g. data protection and codes of conduct that should be adhered to in addition to the recommendations of this document.

2. DEFINITIONS

The following definitions are used within this document. For the purposes of this document, as some Trusts cover multiple sites, an implanting "centre" is taken to mean a single hospital site where cardiac devices are implanted rather than the Trust as a whole. It is accepted that operators (implanters) may work at more than one centre but each centre should conform to the standards within this document.

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

- Permanent pacemakers implanted for bradycardia indications, including leadless pacemakers.
- Cardiac resynchronisation therapy (CRT) devices, also known as bi-ventricular pacemakers, (CRT-P), and bi-ventricular defibrillators, (CRT-D) implanted for heart failure.
- Implantable cardioverter defibrillators (ICDs) implanted for tachycardia with or without bradycardia indications, including subcutaneous ICDs.
- Implantable loop recorders (ILR) and insertable cardiac monitors.

For the purposes of this document, in terms of counting cases, an implanter (operator) is defined as the clinician who is either the main individual performing the case or is present throughout the procedure and plays an active part in the procedure. This does not include merely observing the case or offering advice from within or outside the operating room.

3. TREATMENT INDICATIONS

CRM devices are effective at improving quality of life and reducing mortality. Their use is supported by the National Service Framework for Coronary Heart Disease chapter 8¹, NICE²⁻⁵ and international⁶⁻⁹ guidelines. Although implantation rates across the UK have increased significantly over the past 10 years, they remain below the European average and targets set by NICE³ and other professional organisations. It is recognised, however, that published guidance does not cover all patient groups and may not be appropriate in certain situations. Furthermore, clinical judgement based on published evidence should be used for indications not yet considered by NICE, however, the 2014 NICE Technology Appraisal⁵ addresses many of these areas. It is important to demonstrate compliance with best practice and regular audit of device indications and outcomes is strongly recommended. It is essential that all implanting centres ensure accurate and timely implant data submission to the national CRM database.

For ICD and CRT implantation the development of a multidisciplinary approach to patient selection, management and follow up is recommended. Involvement of physicians (device specialists, imaging and heart failure specialists), physiologists, specialist nurses (arrhythmia and heart failure) to aid in suitability for devices, device selection, optimisation and follow up leads to improved patient outcomes.¹⁰

4. REQUIREMENTS FOR PERFORMING PACEMAKER IMPLANTATION

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

4.1 CARDIOLOGISTS

This section refers to cardiologists implanting pacemakers for bradycardia. Implantation of ICDs and CRT devices requires these skills and additional techniques. Complex device procedure numbers (ICD, CRT-P and CRT-D) can be included with bradycardia pacemaker numbers for the purposes of this section

- a. There should be a minimum of 2 active implanting consultant cardiologists per centre¹¹.
- b. Each implanter should perform a minimum of 35 new pacemaker implants per year¹¹.
- c. Each implanter should have had appropriate training in pacemaker implantation either as an SpR/StR¹³ or in a suitable alternative training post and reassessment / re-training as a consultant if the recommended implantation numbers have not been performed in the last 12 months¹¹.
- d. If an implanter does not perform this number of procedures in a 12 month period then competence should be independently assessed in accordance with StR training guidelines¹¹ (a structured report should be obtained from the trainer/assessor on competency for "sign off." This report should include the number of cases performed and the level of competency as assessed by the trainer/assessor. Assessment should consist of successful completion of 6 DOPS in pacemaker implantation at level 3 by at least 2 assessors).
- e. At least 1 implanter should have current certification in device therapy (BHRS, EHRA or IBHRE).
- f. All implanters must be competent in pacemaker follow up¹².
- g. All implanters must undertake appropriate continuing professional development in device therapy¹² including implications for driving¹⁴.
- h. All implanters must audit their personal complications and share these within their centre and through the National CRM database for clinical governance purposes. If an implanter's complications were to exceed accepted limits¹⁵, practice should be reviewed and advice sought from within the centre or elsewhere within the UK. Operators implanting fewer than 50 new pacemakers per year may need to average their figures over 2 or more years to account for random variation.

4.2 CENTRES

- a. Each centre should perform a minimum of 80 new pacemaker implants per year^{10, 12}.
- b. SpR/StR training requires a minimum of 25 new pacemaker implants per year¹³, therefore centres training a SpR/StR will need to perform more than 105 new implants per year to accommodate this.
- c. In exceptional circumstances, a centre may not be able to meet these minimum numbers but each individual member of the team undertaking the procedures meets the training and competency requirements plus the individual numbers of implants. The rationale for such a service must be clearly justified, the service must meet local clinical governance requirements including documented protocols to deal with complications and must be robustly audited in terms of quality and outcomes with regular external peer review (minimum every two years).

- d. Implantation should be performed in an environment appropriate for sterile procedures¹¹.
- e. All equipment for implantation and management of possible complications must be immediately available, including external defibrillation.
- f. Appropriately trained cardiac physiologists, nurses and radiographers should be present¹¹.
- g. Each centre must maintain a well-managed database of device activity within the hospital IT infrastructure to allow immediate tracing of patients with device advisories and timely electronic submission of data to the National CRM database¹¹.
- h. Each centre must maintain a database of complications to facilitate clinical governance, which must be submitted in a timely fashion to the National CRM database. The specific dataset required will be determined by the BHRS Audit Committee but at a minimum should include the following in relation to first time implants of pacemakers:
 - i. Pneumothorax requiring intervention
 - ii. Haematoma requiring intervention
 - iii. Pericardial effusion requiring intervention
 - iv. Any re-intervention within 12 months from implant.

Complications should be recorded at discharge and at 12 months (9 – 15 months) follow up. If the follow up takes place at a different centre than the implanting centre, it is the responsibility of the follow up centre to submit the 12 months return.

4.3 PHYSIOLOGISTS

- a. There should be at least 2 cardiac physiologists actively involved in pacemaker implantation and follow up in each centre¹¹.
- b. Each physiologist must have had appropriate training in pacemaker implantation and follow up¹¹.
- c. At least 1 physiologist should have current certification in device therapy (BHRS, EHRA or IBHRE).
- d. All physiologists must undertake appropriate continuing professional development in device therapy and associated patient advice¹², including implications for driving according to DVLA guidelines¹⁴ (e.g. time post-implant, relationship to device therapies, impact of cardiac function etc.).
- e. Each physiologist should be actively involved in a minimum of 35 new pacemaker implants per year¹². If a physiologist does not perform this number of procedures in a 12 month period then competence should be independently reassessed. If the physiologist is also following up complex devices (ICD and CRT-D/P), the implant numbers can include these devices.

4.4 NURSES

- a. Implanting centres are expected to develop the role of Cardiac Arrhythmia Nurse Specialist as part of the CRM team at an appropriate (and sustainable) level as recommended in the NSF Chapter 8¹.
- b. It is recommended that arrangements should be made so that nurses are identified as specialist arrhythmia nurses in each implanting 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.

- c. 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.
- d. At least one of the cardiac arrhythmia nurses involved in device management should have current accreditation in device therapy (BHRS, EHRA or IBHRE).
- e. Cardiac arrhythmia nurses must undertake appropriate continuing professional development in device therapy and associated patient advice¹² including implications for driving according to DVLA guidelines (e.g. time post-implant, relationship to device therapies, impact of cardiac function etc.)¹⁴.

5. LEADLESS PACEMAKERS

These devices have only recently been introduced and experience to date is limited. Implantation of these devices requires interventional / electrophysiology experience in order to implant the device. Current recommendations are that they should be implanted only by operators with experience in either electrophysiology or interventional cardiology who are undertaking a high volume of procedures and that within a centre a maximum of 2 consultants should take the lead to concentrate expertise.

6. ADDITIONAL REQUIREMENTS FOR PERFORMING ICD AND/OR CRT-D / CRT-P DEVICE IMPLANTATION (COMPLEX DEVICES)

Implantation of ICDs and CRT devices carries higher immediate and long-term complication rates than 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. As CRT-D and CRT-P devices only differ in terms of the implantation of the RV/ICD lead and both procedures are of similar complexity, the standards applied to CRT should be applied equally to both CRT-D and CRT-P. However, as the indications for CRT-D and CRT-P are similar, it would be expected that centres implanting CRT devices would implant both CRT-D and CRT-P devices.

As already stated, for ICD and CRT implantation the development of a multidisciplinary approach to patient selection, management and follow up is recommended.

All the above standards relating to pacemakers, in terms of the number of cardiologist, physiologists etc. need to be met in addition to the following requirements:

6.1 CARDIOLOGISTS

- a. There should be a minimum of 2 active implanting ICD/CRT consultant cardiologists per centre¹¹.
- b. Each implanter should perform a minimum of 30 new complex device implants or upgrades per year¹⁶⁻¹⁸. However, as complications are minimised by higher procedural numbers¹⁹, an average new pacemaker and complex device implant rate of 60 per year is recommended. As the skills necessary for CRT are different from those required for ICD implantation, if an operator is implanting CRT devices, at least 20 of these devices should be CRT-D/P, however, this number can include upgrades

from pacemakers / ICDs to CRT devices. If an operator implants ICDs, at least 10 devices should be ICDs.

- c. Each implanter should have had appropriate training in ICD and CRT implantation either as an SpR/StR¹³ or in a suitable alternative training post and reassessment / re-training as a consultant if the recommended implantation numbers have not been performed in the last 12 months.¹¹ This should include familiarity with sub-muscular implant techniques and the use of subcutaneous arrays.
- d. If an implanter does not perform this number of procedures in a 12 month period then competence should be independently assessed in accordance with StR training guidelines¹³. A structured report should be obtained from the trainer/assessor on competency for "sign off." This report should include the number of cases performed and the level of competency as assessed by the trainer/assessor. Assessment should consist of successful completion of 6 DOPS in CRT implantation at level 3 by at least 2 assessors and/or 6 DOPS in ICD implantation at level 3 by at least 2 assessors.
- e. For SpR/StR training, consultant implanters must be performing a minimum of 30 new ICD or CRT implants or upgrades per year (40 is desirable).
- f. All implanters must be fully competent in ICD and CRT follow up.
- g. All implanters must undertake appropriate continuing professional development in ICD and CRT therapy¹² including implications for driving¹⁴.

6.2 CENTRES

- a. All patients being considered for ICD/CRT implantation should be fully assessed to determine the aetiology of their cardiac dysfunction or primary arrhythmic condition.
- b. Patients surviving cardiac arrest or sustained ventricular tachycardia require access to assessment by an electrophysiologist.
- c. Each centre should perform a minimum of 60 new ICD or CRT implants per year¹⁶⁻¹⁸ (80 is desirable).
- d. Anaesthetic support must be available for ICD implantation.
- e. In order to assess patients for ICD/CRT therapy, centres must have access to:
 - i. Echocardiography for accurate ejection fraction and dyssynchrony
 - ii. Angiography
 - iii. Cardiac MRI
 - iv. Electrophysiology studies
 - v. Revascularisation before (CABG) or after (PCI) device implantation
 - vi. Anaesthetic support for sedation and general anaesthesia.
- f. Each centre must maintain a database of complications to facilitate clinical governance which must be submitted in a timely fashion to the National CRM database as for pacemakers as detailed in section 4.2 (g).

6.3 PHYSIOLOGISTS

- a. There should be at least 2 cardiac physiologists actively involved in ICD/CRT implantation and follow up in each centre¹¹.
- b. For ICD/CRT implantation, physiologists should have documented experience of a minimum of 25 new ICD implants and 25 new CRT

implants performed under supervision and experience of at least 25 ICD and 25 CRT follow-up evaluations.

- c. Each physiologist should be actively involved in a minimum of 35 new ICD/CRT implants per year¹². If a physiologist does not perform this number of procedures in a 12 month period then competence should be independently reassessed.
- d. All cardiac physiologists involved in ICD/CRT must be fully competent in ICD and CRT follow up.
- e. All cardiac physiologists involved in ICD/CRT must undertake appropriate continuing professional development in ICD and CRT therapy¹² including implications for driving¹⁴.

6.4 NURSES

The nursing requirements for permanent pacemakers outlined above must be in place for an ICD/CRT service. It is desirable for there to be a minimum of 2 specialist arrhythmia nurses in centres implanting complex devices. A psychological support and counselling service for ICD and CRT-D patients is a necessary part of device follow up and should be provided either by the specialist arrhythmia nurse team or the physiologist team. Counselling prior to implant is essential and further counselling as and when required should be made available if a patient is having problems. There should be access to patient information e.g. Arrhythmia Alliance booklets, British Heart Foundation booklets for all device patients. Patient support groups are encouraged where possible as they have been demonstrated to be of an enormous benefit.

7. SUBCUTANEOUS ICDs

Implantation of these devices requires good surgical skills to make an appropriate pocket, tunnel and secure the lead. Current recommendations are that they should be implanted only by experienced transvenous ICD operators who are undertaking a high volume of procedures and that within a centre a maximum of 2 consultants should take the lead to concentrate expertise. All operators should have had appropriate training and completion of a surgical skills course is recommended. All patients must be assessed prior to implant with a vector template, which should include exercise testing, to ensure they are not one of the minority who are at risk of T wave over sensing.

8. REQUIREMENTS FOR CRM DEVICE FOLLOW UP

Device follow-up clinics now encompass all types of CRM devices. Follow up of more complex devices involves knowledge of other features such as impedance monitors to aid in the management heart failure. Device follow up is now almost solely practiced by cardiac physiologists and in some cases specialist nurses. It is important, therefore, that appropriate levels of training are in place and that clinical governance mechanisms and lines of clinical responsibility are clearly established for all follow up procedures.

The objective of device follow up is to ensure that the device is appropriately programmed to deliver therapy whilst minimising any inherent system complication and to ensure that the patient's experience is as safe, comfortable and reassuring as possible.

Device follow-up remains the ultimate clinical responsibility of the consultant cardiologist in charge of the device follow-up service – although it is predominantly a cardiac physiologist run service. Physicians providing such a service must have the required knowledge to do so. A minimum of one physician at a follow up centre should hold current accreditation in device therapy (BHRS, EHRA or IBHRE).

Detailed guidance for device follow up is given in the Appendix, however, the general principles are detailed below:

8.1 PHYSIOLOGISTS

Device follow up clinics should be undertaken with a minimum of two physiologists immediately available, of which the senior physiologist must have evidence of postgraduate training in cardiac rhythm management e.g. current BHRS, EHRA or IBHRE certification, current ILS or ALS certification and evidence of continued professional development in CRM, with knowledge and skills equivalent to Agenda for Change band 7.

8.2 CENTRES

2.1.1 PACEMAKER FOLLOW UP

There should be a clearly defined protocol documenting the lines of communication and support between the lead cardiac physiologist for a bradycardia pacemaker follow up service and the consultant cardiologist responsible for the on-site service to ensure that clinical governance requirements are met. The lead physiologist for bradycardia pacemaker follow up services at non-implanting hospitals must also have a clearly defined protocol documenting the lines of communication with the lead physiologist and consultant cardiologist at the implant centre.

The lines of clinical responsibility must be clearly defined in the local Trust policy. Trusts delivering bradycardia pacemaker follow up services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

2.1.2 ADDITIONAL REQUIRMENTS FOR ICD and CRT FOLLOW UP

There must be a clearly defined protocol documenting the lines of communication and support between the lead physiologist for the ICD and CRT device follow up service and the consultant cardiologist responsible for the on-site service to ensure that clinical governance requirements are met. ICD and CRT follow-up clinics should not be undertaken without a designated cardiologist available on site.

There must be a 24 hour service available to deal with patients admitted with multiple shock delivery, non-delivery of appropriate therapy or other device related issues. This should consist of an appropriately trained cardiac physiologist (as outlined in the above section) and an appropriately trained cardiologist, either on site or with clearly defined, documented and agreed protocols with other implanting centres to provide emergency, on-site, treatment.

The lines of clinical responsibility must be clearly defined in the local Trust policy. Trusts delivering ICD and CRT device follow-up

services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

8.3 TRANSMITTED / REMOTE DEVICE FOLLOW UP

Remote follow-up of cardiac devices can be an extremely useful tool in the management of device patients and can give access to data and diagnostics that normally can be accessed only at a face to face visit. Remote follow-up can be useful in reducing the number of visits that all patients have to make to a device clinic.

9. LEAD EXTRACTION

Lead extraction is an advanced procedure that should be undertaken in specialised centres and is the subject of a separate standards document.

10. END OF PATIENT LIFE MANAGEMENT

- 10.1 Device implantation centres are strongly encouraged to follow a local policy for the management of end of patient life.
- 10.2 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 consideration of domiciliary visits.
- 10.3 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).
- 10.4 Different levels of device therapy termination should be considered specific to the individual case and informed consent must be documented.

11. AUDIT

Device therapy is subject to immediate and long-term complications. There are also frequent advice and safety notices from manufacturers and the MHRA which necessitate timely action.

- 11.1 All implanting centres must collect data on their patients, devices and follow-up which is immediately available and facilitates audit.
- 11.2 All implanting centres must contribute accurate and timely implant data electronically to the National CRM Database including submission of 12 month follow up data. This is a national quality requirement and is audited by the Care Quality Commission.
- 11.3 Data from all local centres on indications for implantation, early and late complications should be presented annually at Network arrhythmia group meetings.
- 11.4 The number of patients receiving single chamber ventricular pacemakers where the indication is sinus node disease 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% or greater of VVI(R) devices in patients with sinus node disease should review their practice in accordance with NICE guidance²⁰.

12. PLANNED REVIEW DATE

December 2016

13. REFERENCES

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