



**STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF  
CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS**  
January 2024 revision

## **1. INTRODUCTION**

This document has been approved by the Council of the British Heart Rhythm Society (BHRS) and is a thorough update. This document will be reviewed by BHRS bi-annually.

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 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.

## **2. DEFINITIONS**

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
- Implantable cardioverter defibrillators (ICDs) implanted for tachycardia with or without bradycardia indications, including subcutaneous ICDs

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. It is essential that all implanting centres submit 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.

#### 4. OUT-OF-HOURS BRADYARRHYTHMIA EMERGENCIES

Patients presenting with bradycardia emergencies, specifically complete heart block, should ideally be directed to a hospital where they can be safely and appropriately managed. Hospitals must have access to facilities or a transfer policy for temporary pacing wires on a 24/7 basis. All patients should be offered early permanent pacemaker implantation. The local cardiac network should oversee regional arrangements.

#### 5. REQUIREMENTS FOR PERFORMING PACEMAKER IMPLANTATION

Safe device implantation requires the appropriate environment, equipment, trained personnel and culture. This section contains information on these areas. The BHRS endorse and recommend the EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators<sup>1</sup>.

##### 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 centre<sup>2</sup>.
- b. Each implanter should perform a minimum of 35 new pacemaker implants per year.
- c. Each implanter should have had appropriate training in pacemaker implantation either as an SpR/StR or in a suitable alternative training post and reassessment / re-training as a consultant (with assessment of competency) if the recommended implantation numbers have not been performed in the last 12 months.
- d. If an implanter does not perform this number of procedures in a 12 month period then competence should be independently assessed. Specialist training guidelines are available to guide competency assessment using a structured report for competency "sign off." This report should include the number of cases performed and the level of competency as assessed by the trainer/assessor. Assessment should

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<sup>1</sup> [EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators: endorsed by the Heart Rhythm Society \(HRS\), the Asia Pacific Heart Rhythm Society \(APHRS\), and the Latin-American Heart Rhythm Society \(LAHRS\) | EP Europace | Oxford Academic \(oup.com\)](https://doi.org/10.1093/europace/euaa367) Burri H et al., EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators: endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin-American Heart Rhythm Society (LAHRS), *EP Europace*, Volume 23, Issue 7, July 2021, Pages 983–1008, <https://doi.org/10.1093/europace/euaa367>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892248/pdf/v078p00403.pdf>

- 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 professional accreditation in device therapy (BHRS, EHRA or IBHRE).
  - f. All implanters must be competent in pacemaker follow up.
  - g. All implanters must undertake appropriate continuing professional development in device therapy including implications for driving.
  - 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 limits, practice should be reviewed and advice sought from regional device leads or BHRS. 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.

## 1. CENTRES

- a. Each centre should perform a minimum of 80 new pacemaker implants per year.
- b. SpR/StR training requires a minimum of 25 new pacemaker implants per year, and centres training a SpR/StR should be performing more than 100 new implants per year.
- 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 should 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 by the local cardiac network (minimum every two years).
- d. Implantation should be performed in an environment appropriate for aseptic procedures. Standard WHO & NICE guidance for preventing surgical site infection should be followed<sup>3</sup>. Wearing indicator under-gloves under plain gloves help identify glove perforation<sup>4</sup>.
- e. Standardised guidance on anti-platelet (ideally avoid) and anticoagulant medications should be used, and electrocautery available (see EHRA guidance).

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<sup>3</sup> <https://www.nice.org.uk/guidance/ng125/chapter/Recommendations#antiseptic-skin-preparation>  
[https://cdn.who.int/media/docs/default-source/integrated-health-services-\(ihs\)/ssi/evidence/appendix10.pdf?sfvrsn=1fac04b\\_2](https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ssi/evidence/appendix10.pdf?sfvrsn=1fac04b_2)

<sup>4</sup> What Role Does a Colored Under Glove Have in Detecting Glove Perforation in Foot and Ankle Procedures? Lee S *Clinical Orthopaedics & Related Research* (2022) 480(12) 2327-2334

- f. Selection criteria for antibiotic pouches should be considered for patients who are at higher risk of infection (e.g. BLISTER score  $\geq 6$ <sup>5</sup>), and the PADIT score is also helpful to identify those at higher risk of infection<sup>6</sup>.

### PADIT score

Low 0-4 0.51%, medium 5-6 1.42%, high  $\geq 7$  3.41%

#### Prior procedures

- 1 1 point
- $\geq 2$  4

#### Age

- $< 60$  2
- 60-69 1

eGFR  $< 30$  1

Immunosuppressed (disease or medications) 3

#### Type of procedures

- Pacemaker / pacemaker box change 0
- ICD / ICD box change 2
- CRT or CRT box change 4
- Pocket / lead revision /add new leads 5

#### Total

- g. The antimicrobial agent Tauropace has been used in patients at high risk of infection and registry data shows encouraging results following its use<sup>7</sup> associated with a reduced risk of infection in a prospective observational study. Chlorhexidine pocket lavage in high risk procedures was associated with a reduced risk of infection without adverse events<sup>8</sup>.

<sup>5</sup> E Maclean, C Monkhouse, et al.

[98/Cardiac implantable electronic device infections: multicentre validation of a novel risk score and its cost-utility implications for antimicrobial envelope use.](#)

European Journal of Arrhythmia & Electrophysiology. 2022;8(Suppl. 1):abstr98 [The BLISTER Score for CIED infection | QxMD](#)

• <sup>6</sup> DH Birnie, AD Krahn et al. Risk Factors for Infections Involving Cardiac Implanted Electronic Devices. J Am Coll Cardiol. 2019;74:2845-54.

<sup>7</sup> Baldauf B. et al. Local and systemic infections after CIED placement with adjunct Taurolidine. HRC 2023.

<sup>8</sup> Diaz JC, Braunstein ED, Cañas F, Duque M, Marín JE, Aristizabal J, et al. Chlorhexidine gluconate pocket lavage to prevent cardiac implantable electronic device infection in high-risk procedures. Heart Rhythm. 2023 Dec;20(12):1674-81

- h. All equipment for implantation and management of possible complications must be immediately available, including external defibrillation with external pacing facilities.
- i. Appropriately trained cardiac physiologists / scientists, nurses and radiographers should be present as dictated by local arrangements.
- j. Each centre should 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 database.
- k. Each centre must maintain a database of complications to facilitate clinical governance, which must be submitted to the National CRM database. Specific complications:
  - Pneumothorax requiring intervention or delay to discharge
  - Haematoma requiring intervention
  - Pericardial effusion requiring intervention
  - Any re-intervention within 12 months from implant.

Complications should be recorded at discharge and at 12 months (9 – 15 months) follow up. Complications should be tracked by NHS number by NICOR.
- k. Each device centre must ensure that they have agreements and arrangements in place that allow their patient's access to MRI scanning.
- l. Extraction referral pathways supported by the local cardiac network should ensure timely extraction is available in patients with infected devices.

## 2. PHYSIOLOGISTS / SCIENTISTS

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

## 3. NURSES

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

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

≥6:

### 1. CARDIOLOGISTS

- a. There should be a minimum of 2 active implanting ICD/CRT consultant cardiologists per centre<sup>11</sup>.
- b. Each implanter should perform a minimum of 30 new complex device implants or upgrades per year. 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 the leads implanted should be left ventricular leads, and 15 defibrillator leads.

BHRS do not wish this guidance to prevent appropriate patient care. Some electrophysiologists, who have implanted high numbers of devices and meet the minimum complex ablation standards, undertake a wide range of interventional electrophysiology procedures requiring on-going skills in wire and catheter manipulation. There are circumstances where electrophysiologists are required to undertake complex devices due to service demands including device implants when on call, covering sickness and many devices are extracted by electrophysiologists with follow on lead implantation. It is important that the local centre ensures devices implanted are inserted and programmed appropriately.

#### RECOMMENDED DEVICE IMPLANT NUMBERS

PACEMAKER ONLY IMPLANTER	Minimum of 35 new implants per year
COMPLEX DEVICE IMPLANTER	See below
NON-CRT IMPLANTER	Minimum 30 new implants
CRT IMPLANTER	60 device implants per year of which 30 should be complex devices (20 left ventricular leads, minimum 15 defibrillator leads)

- c. Each implanter should have had appropriate training in ICD and CRT implantation either as an SpR/StR<sup>13</sup> 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.
- 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 guidelines<sup>13</sup>. 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 therapy including implications for driving.

## 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 / scientist.
- c. Each centre should perform a minimum of 60 new ICD or CRT implants per year

## 3. PHYSIOLOGISTS / SCIENTISTS

- a. There should be at least 2 cardiac physiologists / scientists actively involved in ICD/CRT implantation and follow up in each centre who have appropriate professional certification<sup>11</sup>.
- b. For ICD/CRT implantation, physiologists / scientists 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 / scientist should be actively involved in a minimum of 30 new ICD/CRT implants or upgrades per year<sup>12</sup>. If a physiologist / scientist does not perform this number of procedures in a 12 month period then competence should be independently reassessed.
- d. All cardiac physiologists / scientists involved in ICD/CRT must be fully competent in ICD and CRT follow up & professionally accredited.

- e. All cardiac physiologists / scientists involved in ICD/CRT must undertake appropriate continuing professional development in ICD and CRT therapy including implications for driving.
- f. Device programming should be standardised as per international guidance.

### **Subcutaneous Defibrillators**

Subcutaneous implantable defibrillators are used routinely in current practice. The BHRS recommends they are considered in selected patients needing defibrillators. Developments in the technology include leadless modular right ventricular pacing devices to provide anti-tachycardia (ATP) and bradycardia pacing, and a sub-xiphisternal approach which can deliver ATP in a single device. Centres undertaking S-ICD should maintain a reasonable volume, suggested as more than 10 cases per year, undertake appropriate pre-device screening and have facilities to provide patient comfort options such as deep sedation, general anaesthesia and nerve blocks. In patients who need programmed ventricular tachycardia induction appropriate resuscitation capabilities should be in place, a time out should be undertaken prior to induction, and a failed shock (failure to successfully defibrillate) protocol should be available. Complication data must be submitted to the national audit, and appropriate local governance arrangements should be in place.

S-ICD considered as a first choice:

- Paediatric or adult congenital heart disease patients with no venous access
- Acquired stenosis or obstruction of central veins unless fibroplasty available
- Previous endocarditis or device infection
- Patients at very high risk of infection of endovascular leads: dialysis, immunodeficiencies, cancer, need for a chronic indwelling catheter
- Candidates for cardiac transplantation

S-ICD as a reasonable choice:

- Young patients with an active lifestyle and a long life expectancy
- Inherited genetic arrhythmogenic syndromes (Brugada, Long and Short QT, Early Repolarisation)
- Hypertrophic cardiomyopathy
- Prosthetic heart valves (infection risk)
- Women ("cosmetic" issue)
- Primary prevention patients with ischemic/non ischemic dilated cardiomyopathy
- Secondary prevention patients survivors of out-of-hospital VF

When to avoid the S-ICD:



- Failed pre-implant screening (up to 7% of cases)
- Symptomatic bradycardia requiring permanent pacing
- Previously implanted unipolar pacemaker (sensing/detection pitfalls)
- Systolic heart failure and left bundle branch block, with indication for CRT
- Recurrent sustained monomorphic VT treatable with ATP (unless S-ICD or module able to deliver ATP)
- Anatomic characteristics: thin patients with poor subcutaneous tissue, “pectus excavatum”

## Leadless pacing

Leadless pacing is an option for patients requiring bradycardia pacing (currently VVI with a dual chamber system arriving imminently), and some systems can also provide ATP in combination with an S-ICD. A UK expert consensus statement noted that leadless pacing is regarded as safe and an effective alternative to conventional transvenous pacing.<sup>9</sup> Leadless pacing should take place in a cardiac catheterisation laboratory with access to pericardiocentesis.<sup>10</sup> Shared decision making should be undertaken mentioning the risk of serious acute events including tamponade requiring urgent thoracotomy, device displacement and vascular access issues. Careful attention to contra-indications such as patient habitus and venous abnormalities which could present problems with access and complications from the large sheaths required. In the UK specific guidance is available<sup>2</sup>. UK centres should develop a hub and spoke arrangement if they do not provide implantation locally, follow up should be local and any complications should be notified to the implanting centre and the MHRA (device related). Appropriate training of new operators is essential, and initial implants should be undertaken whilst overseen by an experienced operator.

Implants could be considered for the following patients who

- High risk of infection
- End stage renal disease
- Previous device infection
- Anatomical constraints complicating / precluding transvenous pacing
- Immuno-compromised
- Biological therapies (including immunosuppressants and steroids)
- Undergoing radiotherapy where device close to site of radiotherapy
- High probability of needing indwelling vascular catheters

Implants could be considered for the following groups noting that AV synchrony may be important.

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<sup>9</sup> <https://www.aerjournal.com/articles/uk-expert-consensus-statement-optimal-use-and-clinical-utility-leadless-pacing-systems> accessed 2 October 2023

<sup>10</sup>

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/956252/Leadless-EAG-guidance.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956252/Leadless-EAG-guidance.pdf) accessed 2 October 2023

- Congenital heart disease
- Under 40 years of age
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### Conduction system pacing

This encompasses His bundle (HBP) and left bundle branch area pacing (LBBAP). Conduction System Pacing (CSP) may be considered in a wide range of patients as detailed in international guidelines.<sup>11</sup> Conduction system pacing requires knowledge of electrophysiology and a team of physiologists and implanters dedicated to obtaining good results. There is a learning curve to the techniques. Centres should be aware of the risk of coronary artery perforation and associated septal haematoma with deep septal pacing.<sup>12</sup> Meticulous attention to unipolar (tip to tissue) lead impedance, evoked electrogram (EEG) potentials and paced electrocardiogram (ECG) morphology is important at the time of implantation. Appropriate confirmation of anatomical location with fluoroscopy is helpful. Physiologists / Scientists aid the implant by monitoring lead progress and CSP capture during the implant.

#### Complication of deep septal pacing

<b>LBBAP lead complications</b>	<b>8.3%</b>
• Acute perforation to LV	3.7%
• Lead dislodgement	1.5%
• Acute chest pain	1.0%
• Capture threshold rise	0.7%
• Acute coronary syndrome	0.4%
• Trapped/damaged helix	0.4%
• Delayed perforation to LV	0.1%
• Other	0.7%

His bundle pacemaker follow up requires detailed and meticulous attention to detail to pick up septal pacing, rising thresholds particularly in pacing dependent patients or those where CSP is being used in lieu of CRT. His bundle pacing is associated with rising pacing thresholds, failure to capture during follow up, small sensed R waves, risk of p wave sensing.

Centres considering starting CSP programs outside of research trials should acquire appropriate training to be able to safely undertake initial deep septal implantation for left bundle area pacing (such as using a proctor). It is recommended that implant success, complication and initial follow up is audited. Manufacturer and lead specific guidance should be followed.

<sup>11</sup> [https://www.heartrhythmjournal.com/article/S1547-5271\(23\)02026-X/fulltext#secsectitle0105](https://www.heartrhythmjournal.com/article/S1547-5271(23)02026-X/fulltext#secsectitle0105)

<sup>12</sup> Left bundle branch area pacing outcomes: the multicentre European MELOS study <https://academic.oup.com/eurheartj/article/43/40/4161/6671019> accessed 2 October 2023

### **Recommended knowledge**

- **Implanter** – safe implant technique, awareness of lead behaviour during implantation<sup>13</sup>, unipolar high rate ventricular pacing, effect of programmed stimulation. LBBAP: awareness of fluoroscopy projections needed, unipolar pace mapping, unipolar impedance safety, unipolar paced evoked potential, unipolar morphology of a successful implant, unipolar LVAT, unipolar V6 to R wave V1 interpeak time, QRS duration, ST segment elevation, Left bundle potential to QRS time, fixation beats (skinny ectopics). HBP: non-selective, selective and septal unipolar pacing, H to V time and recognition of prolonged time. Device selection and programming
- **Physiologist / Scientist** - recommended to have completed specific CPD for implantation and follow up. unipolar high rate ventricular pacing, programmed electrical stimulation technique, 12 lead ecg. Projecting EP & pacing screen, set up of filters<sup>14</sup>, unipolar pace mapping, unipolar impedance safety, unipolar paced evoked potential, unipolar morphology of a successful implant, unipolar LVAT, unipolar V6 to V1R time, QRS duration, ST segment elevation, Left bundle potential to QRS time, fixation beats (skinny ectopics). HBP: non-selective, selective and septal unipolar pacing, H to V time and recognition of prolonged time. Device selection and programming

### **Essential equipment**

- 12 lead ECG machine
- Fluoroscopy

### **Recommended equipment**

- EP system
- Slave Display of device programmer

### **Recommended documentation**

- NICOR and local audit
- 12 lead paced ECG
- Left ventricular activation time, QRS duration, V6 to V1 interpeak time, pacing impedance, R wave unipolar, R wave bipolar, R wave morphology unipolar.

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<sup>13</sup> <https://academic.oup.com/europace/article/25/4/1237/7121194?login=true>, <https://academic.oup.com/europace/article/25/4/1208/7121146?login=true>

<sup>14</sup> <https://academic.oup.com/europace/article/25/4/1237/7121194?login=true>

## **8. REQUIREMENTS FOR CRM DEVICE FOLLOW UP**

Device follow-up clinics now encompass many types of CRM devices. Follow up of devices involves knowledge of other features such as detection of heart failure, and ability to deactivate ICDs and program for MRI scanning. It is important that appropriate levels of training are in place and that clinical governance and lines of clinical responsibility are clearly established for all follow up procedures.

Device follow-up remains the ultimate clinical responsibility of the Trust, with a named consultant cardiologist leading the device service – although it is predominantly a cardiac physiologist / scientist 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 be professionally accredited (BHRS, EHRA or IBHRE).

Detailed guidance for device follow up is on the BHRS website; however, the general principles are detailed below:

### **1. PHYSIOLOGISTS / SCIENTISTS**

Device follow up clinics should be undertaken with a minimum of two physiologists / scientists immediately available, of which the senior physiologist / scientist 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.

### **2. CENTRES**

#### **1. PACEMAKER FOLLOW UP**

There should be a clearly defined protocol documenting the lines of communication and support between the lead cardiac physiologist / scientist 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 / scientist 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 / scientist and consultant cardiologist at the implant centre.

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. COMPLEX DEVICES**

The BHRS recommends that all hospitals have local or network arrangements to manage patients with ICDs who are admitted with multiple shock delivery, non-delivery of appropriate therapy

or other device related issues. Referral pathways should exist for decompensated heart failure, VT ablation, awareness that ICD shock therapy is one criteria for referral for advanced heart failure treatment in appropriate patients<sup>15</sup> (I NEED HELP)<sup>16</sup>, and palliative care.

### 3. REMOTE DEVICE FOLLOW UP

Remote follow-up is encouraged, particularly for complex devices as per international guidelines, and this may be alert based where the burden of alerts can be pro-actively managed allowing reduction of calendar based follow up. In-person follow up will be needed for re-programming. As many devices undertake automated measurements, it is important for physiologists / scientists to maintain skills in device troubleshooting.

## 10. Consideration at elective replacement of pacemaker generators (box changes) & management of frailty, dementia and life-limiting conditions with an ICD

BHRS recommend patients whose battery is depleting are identified so that informed shared decision making can occur. Some patients will have straightforward needs for a box change, others may require review to avoid decisions occurring on the day of admission (here shown as green to proceed and red to stop and review)

<b>Wound</b>	Well covered	Peri-erosion
<b>Leads</b>	Normal function	May need replacement
<b>Pacemakers</b>	On-going pacing need	Low frequency of pacing - review need for pacing.  impaired left ventricular function & those with high burden RV pacing who could benefit LV / CSP lead if LV impaired
<b>ICD</b>	Remains indicated	Never had shock - consider reviewing indication

<sup>15</sup> Banner NR, Bonser RS, Clark AL, *et al*

UK guidelines for referral and assessment of adults for heart transplantation  
*Heart* 2011;**97**:1520-1527.

<sup>16</sup> <https://www.mdpi.com/2077-0383/12/16/5217>

<b>ICD</b>	Stable and good functional status	Change in condition e.g. progressive heart failure
<b>All</b>	Well	Severe frailty, significant co-morbidities, profound dementia

Prior to first implantation, it is recommended that the patient is aware defibrillator therapy can be discontinued if their general condition changes, and staff interacting with the patient should be empowered to offer holistic care including broaching shock therapy deactivation.

Patients with progressive conditions e.g. heart failure, those with early dementia and their families should be encouraged to undertake shared decision making whilst they have capacity so that plans are in place for when their condition deteriorates e.g. device therapy discontinuation, not replacing generators. Discontinuation of ICD shocks should be discussed when a patient's prognosis is likely to be limited or their quality of life/comorbidities change and a shared decision making approach should be followed. BHRS recognises this is a difficult area for patients and clinicians alike. BHRS recognises that replacement of a device generator (including pacemakers for bradycardia) may not be appropriate in patients with severe comorbidities. Patients who develop co-morbidities whose ICD battery is depleting should be identified prior to the procedure date, and a discussion should be held around the option of deactivating or leaving the ICD switched off or changing to pacing only (as appropriate). Patients who are under remote follow up should be offered the opportunity of making contact with the centre to undertake shared decision making if they feel their condition has changed.

1. All device follow up centres & integrated care boards (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 domiciliary visits when required.
2. Shock therapy discontinuation should be a shared decision including the treating physician, the patient and where appropriate a representative for the patient (e.g. a relative).
3. Centres should have a mechanism for ensuring that a patient whose device battery is depleting do not attend automatically for a box change without scrutiny of the patients comorbidities, ongoing device need and underlying tissue.

The BHRS has produced guidance on patient choices and ICD therapy discontinuation<sup>17</sup>. The BHRS recommend the Resuscitation Council UK<sup>18</sup> guidance. Other guidance is available, for instance Ontario<sup>19</sup> and Palliative care<sup>20</sup> is listed

## 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.

1. All implanting centres must collect data on their patients, devices and follow up which is immediately available and facilitates audit.
2. All implanting centres must contribute to the National CRM Database including submission of 12 month follow-up data.

## 12. PLANNED REVIEW DATE

## 13. DAY CASE ELECTIVE DEVICE IMPLANTATION

Day case device implantation is encouraged unless overnight admission is required according to local and international guidance. Patients should have a contact telephone number to staff experienced in device complications.

### **Contributors**

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<sup>17</sup><https://bhers.com/wp-content/uploads/2024/01/BHRS-Discontinuation-of-ICD-shock-therapies-towards-the-end-of-life-JANUARY-2024.pdf>

<sup>18</sup> <https://www.resus.org.uk/sites/default/files/2020-05/CIEDs%20Deactivation.pdf>  
accessed 4 October 2023

<sup>19</sup> <https://www.corhealthontario.ca/Implantable-Cardioverter-Defibrillator-Deactivation-A-Guide-for-Health-Care-Professionals.pdf>

<sup>20</sup> <https://www.westmidspallcare.co.uk/wp-content/uploads/SPAGG-ICD-deactivation-guidance-final.pdf>