CLINICAL GUIDANCE FOR THE FOLLOW UP OF CARDIAC IMPLANTABLE ELECTRONIC DEVICES FOR CARDIAC RHYTHM MANAGEMENT

(APPENDIX TO STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF CARDIAC RHYTHM MANAGEMENT DEVICES IN ADULTS)

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1. INTRODUCTION

The continuing evolution of device technology has resulted in the production of a range of devices capable of treating bradycardias, complex cardiac tachyarrhythmias and heart failure management. These devices have multiple modalities and programmable features. The challenge of these treatments lies not only in the implantation of the devices but also in comprehensive follow-up of the implanted devices as part of the lifelong management of the patient. As the number and variety of implanted devices increases so does the burden of follow-up and the knowledge required to optimise and troubleshoot their use. This is compounded by the increasing volume of data provided by devices and the increasing sophistication of programming therapy and detection algorithms. As a result of this increasing complexity, inappropriate or incorrect use of these algorithms or other errors with aspects of device programming may result in serious harm to the patient.

Device follow-up clinics now encompass devices ranging from single and dual chamber bradycardia devices, loop recorders, atrial tachycardia devices, implantable cardioverter defibrillators and cardiac resynchronisation devices. There are also increasing indications for cardiac resynchronisation devices incorporating new modalities such as impedance monitors for treating and monitoring heart failure. The practice of device management follow-up in the UK is often led and practiced by cardiac physiologists and in some cases by specialist nurses. It is essential, 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 clinics. It is also essential that standard procedures are carried out by appropriately qualified personnel.

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

The role of the lead physiologist in device clinics needs to encompass not only device management but also clinical management of patients with a complex range of conditions. Reprogramming of devices is effectively altering a patient's

therapy or "prescription" and it is clear therefore that standards that provide for this to be done safely and effectively are mandatory.

Device follow-up remains the ultimate clinical responsibility of the consultant cardiologist (consultant physician with specialist interest) in charge of the device follow-up service – although it is a cardiac physiologist run service. Physicians providing such a service must have the required knowledge to do so. It is recommended that this includes a recognised CRM device qualification such as BHRS, European Heart Rhythm Association (EHRA) or International Board of Heart Rhythm Examiners (IBHRE) certification.

2. STAFFING QUALIFICATIONS AND TRAINING

All device implants and device follow up centres must have a designated clinical head of department (HoD). The HoD may either be a specialist registered physician or a specialist healthcare scientist. The healthcare scientist (physiologist) lead who is undertaking unsupervised device follow-up must hold BHRS, EHRA or IBHRE certification and have the knowledge and skills equivalent to Agenda for Change band 7.

Depending on the clinic throughput, it is recommended that the clinic should be run by two staff, one of whom meets the lead role competencies.

2.1 HIGHLY SPECIALISED CARDIAC PHYSIOLOGIST

a. A qualified cardiac physiologist (BSc Clinical Physiology or equivalent) with the knowledge and skills equivalent to Agenda for Change band 7
b. Evidence of post-graduate training in cardiac rhythm management techniques, e.g. holds appropriate certification with BHRS, EHRA or IBHRE
c. Hold current ILS or ALS accreditation
d. Evidence of continuing professional development (CPD) in cardiac rhythm management

2.1.1 PACEMAKER ONLY FOLLOW UP CLINICS

a. Perform a minimum of 150 bradycardia pacemaker system follow-up review procedures per year
b. Perform a minimum of 10% of the total follow-up reviews if a centre is undertaking more than 3,000 reviews per year
c. Attend the local implant centre regularly and not less than twice per year to remain familiar with evolving technology (this applies to physiologists leading follow-up clinics at non-implant hospitals)
d. Demonstrate a high level of understanding and knowledge of the full range of diagnostic cardiac investigations

2.1.2 PACEMAKER, ICD & CRT FOLLOW UP CLINICS

a. Perform a minimum of 150 ICD/CRT follow-up review procedures per year
b. Demonstrate a high level of understanding and knowledge of the full range of diagnostic cardiac investigations
c. Must attend an ICD/CRT device course, which has been accredited by BHRS, at least once per year
d. Perform a minimum of 10% of the total follow-up reviews if a centre is undertaking more than 3,000 reviews per year

In some cases it may be appropriate that with the relevant training and competencies that the lead cardiac physiologist may take responsibility for titrating drugs for heart failure optimisation.

2.2 CARDIAC PHYSIOLOGIST

2.2.1 PACEMAKER ONLY FOLLOW UP CLINICS

a. A qualified cardiac physiologist (BSc in clinical physiology or equivalent)
b. Hold current ILS accreditation
c. Has a proven understanding of pacemaker implant procedures
d. Has a proven knowledge of pacemaker technology
e. Has current CPD by attending relevant recognised training study days
f. Is working towards BHRS, EHRA or IBHRS certification

2.2.2 PACEMAKER, ICD & CRT FOLLOW UP CLINICS

a. Has a proven understanding and experience in pacemaker and ICD/CRT device implant procedures
b. Has a proven knowledge of pacemaker and ICD/CRT device technology
c. Has a proven experience in pacemaker follow up clinics
d. Has current CPD by attending relevant recognised training study days
e. Is working towards BHRS, EHRA or IBHRS certification

3. PACEMAKER FOLLOW UP CLINICS

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

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

3.1 PACEMAKER FOLLOW-UP CLINIC OBJECTIVES

a. To optimise the pacing system to the individual patient needs whilst maximising generator life. Safety must be paramount whilst manufacturer guidance and BHRS recommendations should also be taken into account
b. To identify any abnormalities in the pacemaker system and complications of the therapy in order to ensure prompt treatment. This includes the ability utilise device diagnostics to trouble shoot arrhythmias and abnormalities in the pacemaker system
c. To recognise atrial fibrillation and be aware of CHA_2DS_2-VASc scoring to assess the stroke risk to patients and refer, as per local protocol, for further management (which may include consideration of anti-coagulation, ablation and cardioversion)

d. To assess battery status to predict end-of-life of the pulse generator in order to permit timely elective generator replacement
e. To provide patient and family support and education
f. To ensure that safe and accurate measurements are made of device and lead function and that accurate records of each visit are kept. Staff leading the clinic must be able to recognise problems and complications and make the appropriate changes or recommendations
g. To monitor the device implant site and manage any risk of infection
h. To maximise clinical safety and efficiency in line with clinical governance requirements
i. To recognise pacemaker syndrome and minimise RV pacing where appropriate in order to avoid pacing induced heart failure
j. To regularly review patients in line with local, manufacturer and national guidelines
k. To implement relevant advisories from device manufacturers and the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines and advice and notify the MHRA and manufacturer of any problems arising with devices or leads
l. To be able to identify relevant clinical problems and refer patients for immediate or deferred medical care appropriately in line with local policy
m. To provide accurate and complete communication about patient-device interaction and appropriate functionality to GPs and other relevant health professionals

3.2 SUGGESTED PROTOCOL FOR REFERRALS TO A PACEMAKER SERVICE FOLLOW-UP CLINIC AT NON-IMPLANT CENTRES

On receipt of referral from the implant physician or centre, the patient is registered and scheduled for review. The referral information, which should be transferred in line with patient confidentiality, must include:

a. Patient name, address and telephone number
b. Patient GP details
c. Hospital and NHS number
d. Date of birth
e. Referring consultant
f. Pacemaker type and parameters
g. Pacemaker lead models and serial numbers
h. Most recent threshold, battery voltage and lead impedance evaluation results
i. Patient mobility
j. Cross infection issues
k. Indications for implant
l. Medication details

3.3 SUGGESTED APPOINTMENT SCHEDULE

a. Yearly for pacemakers implanted for less than 7-10 years (depending on the manufacturer's recommendation and expected battery longevity)
b. 6 monthly for implants exceeding 7-10 years until the elective replacement indicator is reached
c. 3-6 monthly for devices that exceed the manufacturers suggested longevity

or show decline in battery life

d. At cardiac physiologist's discretion for devices that require closer monitoring e.g. programming/lead issues and monitoring of arrhythmias
e. Some pacemakers are now capable of remote monitoring and therefore clinical visits may be fewer but guidelines for this still need to be established
f. Implantable loop recorders and insertable cardiac monitors should be followed up at a minimum of 6 monthly intervals unless the patient has remote monitoring

Appointment schedules should also depend on the patient's clinical and psychological status and may be required more frequently if there are complications.

3.4 REPORTS

a. A report is generated by the cardiac physiologist in charge of the follow-up clinic; all parameters and clinical details should be documented in department's database and/or the patient's pacemaker notes
b. A copy of the report or a letter is sent to the patient's general practitioner and the referring hospital where appropriate
c. A copy of the report and any information such as programming changes should also be given to the patient if desired
d. All clinics should have a database on which all information about the patient and their device is available in line with BHRS/NICOR national CRM database requirements

3.5 EQUIPMENT AND OTHER ESSENTIAL REQUIREMENTS

A wide range of equipment is essential within the clinic or immediate vicinity of the clinic with access to further cardiac investigations (which need not necessarily be on site). These are listed below:

Equipment essential in the pacemaker clinic (or in the immediate vicinity):

- 12-lead electrocardiograph (ECG) machine with real time recording
- An appropriate range of manufacturer programmers (with appropriate documentation for use of each specific model)
- Emergency 'crash' trolley and defibrillator with integrated pacing function
- Magnet
- Wound treatment pack
- Telephone and/or arrest call button
- Callipers, rate ruler etc.
- Data management system/patient notes
- Sharps box
- Oxygen, suction and relevant adjuncts
- PC in the clinic room for access to device database

There should also be access to MHRA Pacemaker adverse incident reporting on line

Investigations to which the cardiac physiologist should have referral access:

- X-ray facilities
- Ambulatory ECG recording

- Echocardiogram
- Phlebotomy

Cardiac investigations to which it may be desirable to have referral access:

- Exercise stress testing
- Head-up tilt testing

Access for rapid referral of any patient needing urgent admission should also be available.

4. ICD/CRT FOLLOW UP CLINICS

There should be a clearly defined protocol documenting the lines of communication and support between the lead cardiac physiologist for the ICD and CRT 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 physician available on site.

There should be a 24hr emergency service available to deal with patients admitted for multiple shock delivery or non-delivery of appropriate therapy. This should consist of an appropriately trained cardiac physiologist 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/CRT device follow-up services have a responsibility to ensure appropriate arrangements are in place to cover clinic activity (elective or urgent).

4.1 AIMS AND OBJECTIVES

a. To optimise the system to provide delivery of optimal therapy for the individual patient needs whilst maximising generator life. Safety must be paramount whilst manufacturer guidance and BHRS recommendations should also be taken into account
b. To identify any abnormalities in the ICD/CRT system and any complications of the therapy in order to ensure prompt treatment
c. To assess the arrhythmia burden and refer the patient where appropriate for further management such as medication or VT ablation. There should be a protocol in place for this
d. To recognise new onset atrial fibrillation and be aware of CHA_2DS_2-VASc scoring to assess the risk to patients and refer, as per local protocol, for further management (which may include consideration of anti-coagulation, ablation or cardioversion)
e. To ensure that the ICD is appropriately programmed to minimise the risk of inappropriate therapy being delivered and to ensure that effective and appropriate therapy is provided using evidence-based strategies and programming guidelines
f. To understand how to maximise LV pacing in CRT devices in order to maintain effective resynchronisation and to be able to provide optimisation of the device
g. To ensure that there is a clear protocol for referral of patients for heart failure assessment and to recognise signs of an increasing heart failure burden
h. To assess battery status to predict end of life of the pulse generator in order to permit timely elective generator replacement

i. To provide patient and family support and education together with any other healthcare professionals involved in the patient's management
j. To ensure that appropriate patients are given home monitors for remote follow-up and are trained to use them
k. To ensure that safe and accurate measurements are made and that accurate records of each visit are kept. Staff leading the clinic must be able to identify problems and complications and make the appropriate changes or recommendations
l. To monitor the device implant site and watch for any evidence of infection
m. To maximise clinical safety and efficiency in line with clinical governance requirements.
n. To regularly review patients in line with local, manufacturer and national guidelines.
o. To implement relevant advisories from device manufacturers and the MHRA
p. To notify the MHRA and manufacturer of any problems arising with devices or leads
q. To be aware of the need to identify clinical problems and refer patients for immediate or deferred medical care appropriately in line with local policy
r. To provide accurate and complete communication about patient/device interaction and appropriate functionality to GPs and other relevant health professionals.

4.2 IN ADDITION AN ICD/CRT SERVICE SHOULD BE ABLE TO PROVIDE THE FOLLOWING:

a. A knowledge of using manual delivery of ATP in the event of a failure of automatic therapies for VT
b. Knowledge of overdrive therapy for termination of atrial flutter in patients who have developed this and who are appropriately anti-coagulated
c. A psychological support and counselling service for ICD patients is a necessary part of device follow-up and should be provided either by the physiologist team or an arrhythmia nurse team. Counselling prior to implant is essential and further counselling as and when required should be made available. Patient support groups are encouraged where possible as it has been proven that there is an enormous benefit to be gained.
d. Deactivation of the ICD either temporarily or permanently in the event of terminal illness in a patient or surgical interventions should be available as per local protocols.

5. TRANSMITTED/REMOTE DEVICE FOLLOW-UP

In the era of communication technology, new options are now available for following-up patients implanted with pacemakers, ICDs and CRT devices. Most device companies either offer devices with wireless capabilities that communicate automatically with home transmitters or manually by the patient using a telemetry wand, which then relays data to the device clinic, thereby allowing remote patient follow-up and monitoring.

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 only be accessed at a face to face visit. Remote follow up can be

useful in reducing the number of visits a patient has to make to a device clinic and should be considered in the following groups of patients:

a. Where more frequent monitoring of arrhythmias such as AF and VT is necessary
b. Device or leads under advisory
c. Management of ERI (patients with <12 months of estimated battery life)
d. Heart failure management
e. Patients in nursing homes, rest homes and any patient who may have difficulty in attending their local device clinic

All clinics using remote follow-up will need to have procedures in place for analysing the patient transmissions and taking the appropriate action.

The cardiac physiologist supervising such a remote service will require the same level of expertise and training as the cardiac physiologist leading a clinic attended directly by patients.

Remote follow up protocols must be inline with BHRS standards of device follow up, device manufacturers and the European taskforce group on regulations relating to remote device follow up and agreed by the responsible consultant cardiologist / lead cardiac physiologist.

6. CLINIC PROCEDURES

6.1. All device follow up clinics should work to a standard procedure/protocol. This may be locally developed but should incorporate the minimum requirements set out in these guidelines.

6.2. A formal quality assurance system should be in place including regular review meetings and regular process audits to ensure compliance with departmental and BHRS standards.

6.3. The typical clinic time for cardiac device follow up including clinical assessment should be 20-30 minutes for a standard device follow up e.g. pacemaker or ICD and 45 minutes for complex device follow up e.g. CRT (or patients requiring more detailed evaluation).
This is not mandatory and may vary according to the presenting problems/complications.

6.4. Device follow-up should be in line with BHRS standards

6.5. An electronic report database should exist with a facility to store device reports as PDFs. Data must be submitted in a regular and timely fashion with all appropriate fields completed to the UK central cardiac rhythm management database held by NICOR.

6.6. A procedure for device follow-up should include the following where possible:

a. Recording of an ECG rhythm strip to verify device function and monitoring this throughout the check
b. Maintenance of device function throughout check
c. Identification of the device and leads from the patient records
d. Assessing the clinical condition of the patient and identifying any changes in status from previous visits including recognition of AF either as new onset or an increased burden and identifying the associated risk factors (there should be a local protocol in place for handling this situation)

e. Initial interrogation of the device and recording of any relevant information
f. Assessment of device battery status and comparison with previous records
g. Safe testing of device and lead status including thresholds for sensing and capture as well as impedance measurements
h. Assessment of diagnostics, events and appropriate counters/histograms for rate assessment and appropriate function
i. Appropriate troubleshooting for complications/problems using other investigations where necessary
j. Appropriate reprogramming of the device to ensure that optimal settings for clinical outcomes are provided for the patient
k. Recording all of the above
l. Checking final settings and ensuring that any changes have been fully and appropriately documented and checked to ensure patient safety
m. Appropriate scheduling of the next appointment or referral
n. Ensuring that device registration has been undertaken and that all patients have their registration/ID cards and all appropriate information.
o. A PC is recommended in rooms used for cardiac device follow up for access to cardiac device databases and for generating reports

A checklist that may be useful for all clinics is shown in the table below.

LOW VOLTAGE/ HIGH VOLTAGE	HIGH VOLTAGE
Correct pacing mode Appropriate lower pacing rate / sleep rate Appropriate upper tracking rate Appropriate upper sensor rate Appropriate rate response Assessment of percentage of ventricular and atrial pacing Assessment of percentage biventricular pacing Assessment of atrial and ventricular threshold measurements and trend data Assessment of atrial and ventricular impedance measurements and trend data Assessment of atrial and ventricular sensing measurements and trend data Battery voltage/impedance Far field R wave sensing T-wave oversensing Myopotential oversensing Optimisation of atrial and ventricular outputs Anodal capture/stimulation Diaphragmatic / phrenic nerve stimulation Rate drop assessment (is used) Wound evaluation Swollen ankles Increased breathlessness Assessment of heart failure New onset AF Assessment of AF burden Assessment of antiarrhythmic, anticoagulation and heart failure medications in line with local guidelines	Therapies ON Correct zone programming Correct VT/VF detection programming Assessment of shock lead impedance measurement(s) and trend data Capacitor charge time Appropriate programming of ATP/ shock therapy Evaluation of VT burden (including non-sustained VT)

These follow up guidelines were produced by Sue Jones and Stuart Allen on behalf of BHRS Council. The document was reviewed and approved by BHRS Council.