Clinical Guidance by Consensus

Guidance Information for Managing Bradycardia Pacemaker Follow-Up Clinics

British Cardiovascular Society
The Society for Cardiological Science and Technology

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Introduction

This guidance has been developed by the Society for Cardiological Science and Technology (SCST) by gathering and presenting the evidence for best practice to improve the equity and quality of services throughout the United Kingdom. The British Cardiovascular Society has approved this guidance and SCST have forwarded this guidance for approval to Heart Rhythm UK (HRUK).

This guidance is based on existing research and on the knowledge and experience of practitioners. Where research based evidence is not yet available consensus decisions have been made. As the research base is constantly growing, SCST will regularly review the guidance to ensure that they continue to reflect current best practice.

Background

Implantation is only the initial phase in the lifelong management of the patient with a pacemaker. The challenge of this treatment lies in the comprehensive follow-up of the implanted pacemaker. As the number of implanted devices increase so does the burden of follow-up. This is compounded by an increasing volume of data provided by devices, and the increasing sophistication of programming therapy and detection algorithms. There are some general guidelines on pacemaker follow-up provided by national organisations.

To follow up patients with implanted devices adequately the clinics have to be properly resourced. This includes real estate, equipment, and appropriately trained personnel. A dedicated area for pacemaker follow-up should be provided which enables the patient to have their review performed in privacy and safety.

Due to the combination of increased numbers of implanted bradycardia pacemakers, the complexity of these devices, new recommendations for the review and follow-up of bradycardia pacemakers, and the reduction in junior doctors working hours, pacemaker follow-up is increasingly performed by non-medical staff such as Cardiac Physiologists (CPs) and other health care professionals e.g. nursing staff.

Important Note:
Throughout this document the personnel performing the pacemaker follow-up procedure are referred to as “Cardiac Physiologist” or “CP” as it is likely that this professional group will carry out most pacemaker follow-ups. However, the guidance set out in the text is best practice and should be followed by any professional performing pacemaker follow-up procedures.

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1 Paul R Roberts Follow-up and Optimisation of Cardiac Pacing Heart 2005; 91:1229–1234.
Bradycardia Pacemaker Follow-up Clinic Objectives:

1. To optimise the pacing system to the individual patient need whilst maximising generator life. Safety must be paramount whilst manufacturer guidance and HRUK recommendations should also be adhered to.
2. To identify any abnormalities in the pacemaker system and complications of the therapy in order to ensure prompt treatment.
3. To assess battery status to predict end-of-life (EOL) of the pulse generator in order to permit timely elective generator replacement.
4. To provide patient support and education.
5. To ensure that the patient’s experience is as safe, comfortable and reassuring as possible.
6. To ensure that safe and accurate measurements are made and that accurate records of each visit are kept. Staff leading the clinic should be able to recognise problems and complications.
7. Maximise clinical safety and efficiency in line with clinical governance requirements.
8. Regularly review patients in line with manufacturer and HRUK guidance.
10. Provide accurate and complete communication about patient-device interaction and appropriate functionality to General Practitioners (GPs) and other relevant health professionals.

Suggested Procedure for Referrals to a Bradycardia Pacemaker Service Follow-Up Clinic

On receipt of referral from implant physician/centre the patient is registered and scheduled for review. The referral information must include:

i. Patient name and address and telephone number
ii. Patient GP details
iii. Hospital/NHS number
iv. Date of birth
v. Referring consultant
vi. Pacemaker type and parameters
vii. Patient mobility
viii. Cross infection issues
ix. Indications for implant

- The patient is reviewed at regular intervals in accordance with department and manufacturers guidance.
- An appointment letter is forwarded to all patients at least three weeks prior to appointment.
Staffing: Qualifications and Training

Ideally, the clinic should be manned with two staff, one of who meets the lead role competencies. The second staff member can be undergoing training.

Lead Cardiac Physiologist

- A qualified Cardiac Physiologist (BSc Clinical Physiology or equivalent)
- Evidence of postgraduate training in cardiac rhythm management techniques, for example, HRUK Certification of Accreditation or current NASPE/IBHRE pacing exam/AP
- Hold current ILS or ALS accreditation
- Evidence of Continual Professional Development (CPD) in cardiac rhythm management
- Perform minimum of 100 follow-up review procedures per year
- Attend local implant centre regularly and not less than twice per annum to remain familiar with evolving technology
- Demonstrate high level of understanding and knowledge of the full range of diagnostic cardiac investigations

Cardiac Physiologist

- A qualified Cardiac Physiologist (BSc Clinical Physiology or equivalent)
- Hold current ILS accreditation
- Proven understanding of bradycardia pacemaker implant procedures
- Proven knowledge of bradycardia pacemaker technology
- CPD by attending relevant training study days

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.
- Range of manufacturer programmers (with information booklets for 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.

There should also be access to MHRA Pacemaker adverse incident reporting forms.
Investigations to which the cardiac physiologist should have referral access:
- X-Ray facilities.
- Ambulatory ECG Recording.
- Echocardiogram.

Cardiac investigations to which it may be desirable to have referral access:
- Exercise Stress Testing.
- Head-up Tilt-Table Testing.

Standard Procedures

1. All staff working in this clinical area must have undertaken theoretical and practical based training to ensure that they work in a safe and accurate manner. They will hold a comprehensive knowledge of cardiac anatomy and be able to demonstrate competence in the rapid and accurate interpretation of the 12-lead ECG. They should also be familiar with the indications for bradycardia pacing (as per HRUK/NASPE/IBHRE guidance) and the possible complications and contra-indications. They should have an extensive knowledge of the range of normal measurements for such systems and of where further information/advice can be sourced.

2. All Staff must understand the need for the reporting of adverse events primarily to the Physician responsible for the patient and their further responsibility in reporting any device and/or system errors to the MHRA.

3. All patients will be linked to a recordable ECG source, preferably via the programmer for their device.

4. Correct patient demographic details will be on record and verified as correct with the patient prior to any intervention or testing.

5. Device therapy should be maintained throughout all procedures. If brady/tachy therapies require suspension then adequate alternative means of therapy must be available, e.g. external defibrillation, temporary pacing, and ECG monitoring. Patients should be monitored throughout the review, local nursing staff should be notified of such changes and documentation should be made in patient medical notes.

6. The integrity of the “set up” must be maintained throughout the procedure.

7. During the procedure a detailed log of the measurements and tests performed should be kept on the “permanent pacemaker (PPM) follow-up sheet”, patient notes or database as appropriate.

8. At the end of the procedure the original programming must be restored, unless appropriate changes have been made. All changes made to the device must be clearly identified and final parameters recorded dated and signed. Pacemaker records must be signed and dated as appropriate by lead CP or Consultant Cardiologist as per local protocol.
9. In the event of a Cardiac Arrest the CP will perform life support and defibrillation as appropriate in line with the current European Resuscitation Council guidelines\(^3\). A crash call will be initiated immediately in accordance with department policy.

**Protocol**

1. Identify the patient and verify their demographic details, against the stored records. Ensure that Address and GP details are current.

2. An ECG should be performed where indicated.

3. Identify the manufacturer and model of the generator from records. If this is not available, consider asking the patient for their European PPM Identification card, checking department database or patient notes for implant information or discharge letters. If the patient is a new referral or emergency from another centre then every effort should be made to obtain the implant details before proceeding further. In the event of none of the above being possible, then consideration should be made to ask a physician to request an X-ray of the device for identification purposes.

4. Once the device and patient have been correctly identified the relevant manufacturer specific programmer should be set up and turned on.

5. Surface ECG limb leads should be attached to the patient and a clear diagnostic quality tracing (where possible) obtained, prior to interrogation or programming of the device.

6. All tests should be performed with the patient sitting in a semi-recumbent position. If this is not possible for medical reasons then adequate precautions should be taken to ensure that the patient is supported, particularly during threshold checks.

7. Initial program setting of the device should be noted/printed if necessary.

8. The device testing should, where possible, include:
   - Intrinsic pulse amplitudes measured in milliVolts, including documentation of underlying rhythm, if any.
   - Pacing thresholds in all available leads, measured in either pulse width or voltage. Threshold checks should be performed in the most physiological mode possible.
   - Lead impedances measured in Ohms.
   - Battery voltage, and/or current and battery impedance.
   - Percentage paced and sensed since last check.
   - Heart rate histograms.
   - Significant events and diagnostics (e.g. high rate episodes, mode switches, rate drop, ATP, high voltage therapies).

\(^3\) European Resuscitation Council Guidelines www.erc.edu/index.php/guidelines
• Any other relevant testing.

9. Documentation should be made in the patient pacemaker record of all tests and abnormalities.

10. After device testing and evaluation, consideration should be given to optimising device function. Any decision to change a device’s functionality must be agreed with a physician or the Lead CP with relevant experience and the name of the authorising physician/CP clearly identified with the changes and rationale.

11. Sudden changes in threshold or lead impedances should be investigated further, consider changes in medication regime, other cardiac events or surgery. The conclusion to the above investigations may require a chest x-ray to confirm the systems integrity. X-rays for such purposes should be Anterior Posterior and Left Lateral in order to show the system optimally, they must also be over-penetrated in order to reduce soft tissue images and show a clearer view of the PPM system hardware.

12. If device function is acceptable, the next appointment should be scheduled for a maximum of 12 months.

13. Devices that show decline in battery life should be scheduled for 3-month follow-up. Devices that require closer monitoring because of lead problems, medical reviews, programming issues etc, should be followed up at an interval of the lead CP’s discretion and correlate with any recall/advisories generated from the device manufacturer.

14. Patients whose devices indicate End-of-Life (EOL) characteristics should be brought to the immediate attention of the implanting consultant or in accordance with local policy. The patient’s telephone number should be taken with a view to imminent replacement. Those showing Elective Replacement Indicators (ERI) should be given a 1-month covering appointment and contact should be made with the physician/physician’s secretary (preferably by e-mail). Other examples of good practice are to make an R-wave measurement and record the patients escape rate. If applicable the pacemaker could then be reprogrammed to bipolar pace and sense to facilitate the box change process. Relevant information, for example Warfarin status, would be useful when contacting the physician.

15. The PPM follow-up sheet should be complete with all results/therapies, changes made and reasons for change detailed.

16. A letter should be printed/drafted for the GP and left with the patient pacemaker record for the consultant/Lead CP to sign. This letter informs the GP of the date and results of the patient’s follow-up.

17. Pacing statistics must be completed, chart counter-signed, patient chart correctly filed and any changes to the database saved.
18. All relevant data should be entered onto relevant computer database as outlined in SCST “Supplemental Technical Information relating to Bradycardia Pacemakers” document.

**Authors and acknowledgements**

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