

Guidelines for Pacemaker Follow-up: REPORT OF A BRITISH PACING & ELECTROPHYSIOLOGY GROUP (BPEG) POLICY CONFERENCE ON PACEMAKER FOLLOW-UP

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Introduction

Follow-up is a vital part of pacemaker treatment which demands staff training and experience and equipment availability. There exists a need to define as accurately as possible this aspect of pacemaker practice for patient benefit and apply it to the present United Kingdom health care system. This was addressed by a Policy Conference conducted by the British Pacing and Electrophysiology Group on 14th January 1993. This conference was attended by speakers and delegates drawn from all kinds of pacemaker practice in this country [Appendix 1]. Its recommendations are presented here and provide a logical next step beyond BPEG's recommendations for pacemaker prescription for symptomatic bradycardia.[1] .

Present situation

Pacemaker follow-up is of a very high standard in some centres in the United Kingdom. Basic follow-up is widely conducted in this country but in some instances it is with minimal facilities, technical knowledge, skill and medical input; in a few districts no follow-up service exists. After the first year, patients are usually seen annually and then more frequently towards the end of pacemaker battery life. A service is often provided for large communities for example 100,000 to more than 3,000,000. Equipment in its most basic form consists of an electrocardiograph, a magnet and hand-held electronic monitor for stimulus-stimulus interval and pulse duration measurement. Records are sometimes rudimentary. Some follow-up clinics have access to simple waveform analysis devices and keep in close touch with a major centre by telephone or fax. In a few cases follow-up clinics provide a small number of home visits for very immobile patients.

Immediate future

The programmability and increasing complexity of pacemakers will impinge on follow-up at all levels. The responsibility for programming should always be that of the supervising physician; in many cases it is performed by a cardiac technician under physician supervision, but the necessary experience of either or both the physician and the technician is not universal. A full range of

programmers for the generators under follow-up is not always available.

In the new British health care system, introduced in 1991, an increase in the number of pacemaker centres has occurred and further increases are expected. There is concern over the lack of a national policy for the development of pacemaker services and determination of both human and technical resources which are necessary. The U.K. pacemaker pricing structure is much lower than in other western countries and does not allow for an increased level of manufacturer support for small clinics. A profusion of clinics will necessarily dilute resources and as a result the industry may be forced to consider such measures as the sale or lease of programmers [presently provided free of charge in most instances] and charging for the provision of advice by their technical personnel. Alternatively, the cost of the pacemaker generator and/or leads may be increased.

Aims of a pacemaker follow-up clinic.

The aims of a pacemaker follow-up clinic are clearly definable and are listed in Table 1. The goal of this document is to attempt to secure as full a service, as widely as possible, within the limits of the facilities which can be provided. The emphasis is placed on service provision at District General Hospital [DGH] level with close co-operation, where appropriate, between DGH and regional or specialist centre. Within the context of such a framework the recommendations of the Policy Conference are given below.

Equipment required in a pacemaker follow-up clinic.

In a pacemaker centre the equipment considered necessary for adequate follow-up includes full facilities for resuscitation, and is given in Table 2. This document does not aim to describe the clinical practice of pacemaker follow-up but refers the reader to recent texts on the subject [2.3].

Functional aspects of a pacemaker clinic

Accurate record keeping is of the utmost importance with, available to the clinic, an implant report, discharge summary, previous follow-up notes, medical letters and the pacemaker's programme. Files in the database should be created for procedures, generators and leads, in order to facilitate traceability in the event of an advisory or recall. These functions are easily handled by a personal computer which should be linked to the National Pacemaker Database. [NPDB].

Patient support and education is an essential part of the follow-up clinic's function aided by the British Heart Foundation booklet on pacemakers[4], the manufacturer's literature and any that is locally available. Prior to hospital

discharge, the European pacemaker registration card should be provided to the patient, together with an explanation of the recommendations concerning driving motor vehicles, danger and lack of danger of electrical interference and a contact telephone number where advice is available (24 hours). It may be necessary to reprovide some or all of this information at subsequent follow-up attendances.

A competent clinic should have house rules where certain procedures are followed under all usual circumstances. The clinic should inform all doctors caring for each patient in a comprehensible manner, bearing in mind that those not trained in pacemaker medicine will not understand jargon. Patients who fail to attend for routine follow-up must be persuaded and encouraged so to do. The cause of any death should be established with reference to pacemaker function and the NPDB [Appendix 2] should be informed; the appropriate generator and lead manufacturer should also be informed.

Any documented or suspected generator or lead malfunction should be reported to the Adverse Incident Centre at the Medical Devices Agency of the Department of Health [Appendix 2] as well as the NPDB and appropriate manufacturers.

Procedures at pacemaker follow-up may be divided into routine and "troubleshooting". These are listed in Tables 3 and 4.

DGH Cardiologists who have special interest or training in pacing can provide a full service, given that sufficient human and equipment resources are made available to them. It is anticipated these cardiologists will have arrangements with a nearby cardiac surgical centre for the undertaking of procedures which require its availability such as lead extraction. DGH cardiologists who have no special interest or training are strongly encouraged to seek training or help from a pacemaker centre in their neighbourhood. There are other areas of possible co-operation between a DGH unit and pacemaker centre which may be, for example; a visiting cardiologist to perform procedures or to do a follow-up clinic, patient attendance alternately at the unit clinic and the pacemaker centre's clinic or for the centre to provide a mobile clinic with staff and equipment to the unit. The aim is to deliver the best possible service as locally as possible for pacemaker patients as they are often elderly and sometimes infirm.

Advice and device specific training in the clinic may be given by the representatives of pacemaker manufacturers but patient management must be by the responsible physician and other members of the team supervised by the physician. As the equipment provided by pacemaker manufacturers, such as programmers, should not be assumed to be free of charge and price packages negotiated with Purchasing Authorities must take this into account.

The indications for patient attendance at a pacemaker centre for follow-up are where there is a lack of medical expertise or technical equipment (specific e.g. programmers and general e.g. tilt test) or lack of trained technicians or inability to undertake troubleshooting, and management of the medical and surgical problems of pacing, including pacemaker syndrome. Good communication

between the DGH unit and the specialist pacemaker centre will help to solve these problems.

Telephone monitoring of patients involves additional expense and adds to the follow-up burden. It remains largely unapplied in the UK despite its technical feasibility but it is of value for partial follow-up for the very disabled and for those living at great distances from the clinic.

Adverse events

In January 1993 the Active Implantable Medical Devices Directive came into force throughout the European Union with a transition period until 1st January 1995. This determines that adverse incidents must be reported by manufacturers to the Competent Authority as a statutory obligation which in the UK is the Medical Device Agency (MDA) of the Department of Health. Thus, the onus to report now falls on the manufacturer but the system will only function if clinicians take the initiative to report both to manufacturers and to the Adverse Incident Centre of the MDA. Thus, the previous voluntary reporting system will continue to run in parallel with the new manufacturers reporting obligation. When an adverse incident is reported the MDA will conduct a full investigation with input from clinical experts. This may result in the issuing of a Pacemaker Technical Note, modification or withdrawal of a device. When any advisory is issued it is important that all implanting and follow-up centres are informed as patients may be mobile from one centre to another. Pacemaker centres and follow-up clinics will receive three communications in such events: one from the manufacturer, the second from the MDA and a third from the NPDB (with clinical advice where appropriate from BPEG) which holds the patient's names and device model and serial numbers. These will aim to provide sufficient information for patients at risk to be identified and appropriate action to be taken. All pacemaker centres and follow-up clinics have the responsibility of informing the MDA of their existence so that they can receive information.

Training for the pacemaker clinic

BPEG together with the Society of Cardiological Technicians plan to establish a core curriculum which is taught by them around the country. Other courses may be co-opted into the programme. At present there is a two week BTEC course in pacing occurring twice per year which is approved by BPEG. Competence is established at the end of each course by examination. Physicians and technicians may also consider demonstrating their competence by taking the North American Society of Pacing and Electrophysiology's examination (NASPEXAM). At present there is no British equivalent of this examination. The North American Society holds separate annual examinations for physicians and technicians. The above planned courses in the UK will expect to offer updating with continuing medical education credits. Opportunities for continuing medical education for both physicians and technicians exist in this country at the BPEG and British Cardiac Society Annual General Meetings and at international

meetings. Two peer review journals: "Pacing and Clinical Electrophysiology", published in the USA and "European Journal of Cardiac Pacing and Electrophysiology" published in Munich, Germany are available, as well as articles in other medical and cardiological journals.

Staffing, skill and training levels and quality control

The Recommendations of the Policy Conference in these respects are given in Table 5.

The migratory patient

Pacemaker patient follow-up should be transferred to a local centre if a patient moves home. The transfer of follow-up should be made with the co-operation of the implanting (and previous follow-up) centre. The implications are that the new clinic takes over the traceability responsibility and that copies of the patient records are transferred.

Conclusion

With these recommendations of the Policy Conference, BPEG anticipates that pacemaker patient care will improve at all levels. These recommendations emphasise close co-operation between the physician, technician and centre responsible for pacemaker patient care.

References

1. Clark M, Sutton R, Ward D, Camm AJ, Rickards A., Ingram A, Perrins EJ, Charles R, Jones S, Cobbe S. Recommendations for pacemaker prescription for symptomatic bradycardia. *Br. Heart J.* 1991 66: 185-91
2. Furman S, Hayes DL, Holmes Jr DR. *A Practice of Cardiac Pacing.* Futura Publishing Company Inc, Armonk, New York, USA 1993
3. Sutton R, Bourgeois I. *The Foundations of Cardiac Pacing Pt.1.: an Illustrated Practical Guide.* Futura Publishing Company Inc. Armonk, New York, USA 1991.
4. British Heart Foundation pacemaker booklet. British Heart Foundation. London, UK. 1990
5. Definitions of medical and technical officer (MTO) competency and training levels. Department of Health.

Table 1

AIMS OF A PACEMAKER CLINIC

1. Optimisation of the pacing system to the patient's needs: together with safe maximisation of generator life.
2. Identification of abnormalities in the pacemaker system and complications of the therapy in order to permit prompt therapy.
3. Prediction of end-of-life of the pulse generator in order to permit elective (non-urgent) change of the pulse generator.
4. Provision of patient support and education.
5. Accumulation of a database that offers information on present and past pacing systems for each patient and general data on the function of pulse generators and leads from as wide a field of use as possible [including a link to the NPDB].
6. Provision of training opportunities for medical and para medical personnel.
7. Provision of a clinical cardiological follow-up service where this is appropriate. In some cases this is provided by a separate clinic or, alternatively, at another medical facility.

Table 2

EQUIPMENT FOR PACEMAKER FOLLOW-UP CLINICS

ESSENTIAL

- 1.- Resuscitation equipment
- 2.- Multi channel electrocardiograph
- 3.- Magnet
- 4.- Relevant range of pacemaker programmers [for devices in use in that centre]
- 5.- Manuals for all relevant pacemaker and programmers
- 6.- Electronic device for measurements of stimulus-stimulus intervals and pulse duration. This device should be suitable for the analysis of both single and dual chamber models.
- 7.- Contact telephone numbers of all relevant manufacturers or their UK agencies

8.- File of Department of Health Pacemaker Technical Notes and notices from manufacturers.

9.- Access to X-ray facilities, exercise testing, 24 hour ambulatory electrocardiography.

10.- 24 hour telephone answering facilities manned by competent staff.

11.- Access to temporary pacing facilities (chest wall, trans-oesophageal and / or transvenous)

12.- Facilities to admit patients at emergencies at any time.

RECOMMENDED

1.- Electrocardiographic screen monitoring

2.- Equipment for pulse waveform analysis; a dedicated device with or without a measuring oscilloscope

3.- Computer for patient database with modem link to the NPDB

4.- External pacemaker and electrodes to provide chest wall stimulation for implanted pacemaker inhibition.

5.- Reference medical and technical textbooks

6.- Access to tilt testing and invasive electrophysiological testing.

All equipment should be properly maintained and calibrated.

Table 3

Routine pacemaker follow-up

Essential

a. Patient Assessment

1. symptoms

2. skin overlying the pacemaker system

b. > 12 sec multi channel ecg rhythm recording with and without magnet application over the generator.

c. lead stability testing. respiratory tests and lead integrity by generator manipulation.

- d. end-of-life check. use of a device specific programmer is mandatory. acquiring generator telemetry concerning lead function where available.
- e. verification of pacing and sensing functions by threshold assessment using the programmer and / or (where appropriate and applicable) magnet application.
- f. recording and communicating all the above as appropriate.

Recommended

- a. rate response behaviour by simple exercise testing e.g. standard hospital walk with rate histogram analysis where available.
- b. acquiring generator telemetry of holter data where available.
- c. pacemaker stimulus waveform analysis.

Table 4 Troubleshooting in pacemaker follow-up

Essential

- a. crosstalk evaluation and susceptibility to pacemaker mediated tachycardia.
- b. wenckebach point evaluation in aai or aair systems.
- c. temporary reprogramming of the generator in order to expose latent problems.

Recommended

- a. pulse waveform analysis for lead insulation or conductor fracture.
- b. exercise testing to optimise the pacemaker's programme or to evaluate state of chronotropy.
- c. chest wall stimulation to assess the underlying rhythm (alternatively, the pacemaker rate can be temporarily programmed to a low rate).

detection of intermittent faults may require all the facilities of a cardiac clinic including 24 hour ecg/blood pressure monitoring, x-rays, tilt testing electrophysiological study or reoperation.

Table 5

Skill training and competence in

pacemaker follow-up

level 1 follow-up at non-implanting centres*

<input type="checkbox"/>	medical staff: one cardiologist with an interest in and training in pacing
<input type="checkbox"/>	technical staff: one technician minimum grade mto2 (5)
<input type="checkbox"/>	training: technician has attended an approved course on pacing
<input type="checkbox"/>	quality control: monitored by cardiologist with involvement of the implanting centre when appropriate.
<input type="checkbox"/>	audit.
<input type="checkbox"/>	Equipment: sufficient for routine follow-up and troubleshooting

level 2 follow-up at implanting centres

medical staff: two cardiologists or physicians with an interest in cardiology or one of the above with one committed and trained clinical assistant.

<input type="checkbox"/>	one member of junior staff in training
<input type="checkbox"/>	technical staff: two technicians minimum grade mto2
<input type="checkbox"/>	training: as for level 1 for both technicians
<input type="checkbox"/>	quality control: maintained by lead consultant of the unit and by audit
<input type="checkbox"/>	equipment as for level 1

level 3 follow-up at specialist pacemaker centres **

medical staff: two cardiologists with an interest in pacing

<input type="checkbox"/>	one or more members of junior staff in training
<input type="checkbox"/>	training: as for level 1 for all technicians
<input type="checkbox"/>	quality control: as for level 2
<input type="checkbox"/>	equipment: as for level 2 but additionally cardiac surgical facilities available.

* at present, a lower level of pacemaker follow-up exists for non-programmable VVI units.

** these may be regional cardiac centres.

Appendix 1

Invited participants at the BPEG pacemaker follow-up conference

under the chairmanship of Richard Sutton

Roger Blackwood

Wexham Park Hospital, Slough, Berks on basic follow-up, the DGH view and medical and technical competence.

Ann Ingram

Westminster Hospital, London SW1 on technical equipment and record keeping [now Royal Brompton Hospital]

Sue Jones

St George's Hospital, London SW17 on special procedures

Michael Joy

St Peter's Hospital, Chertsey, Surrey on the DGH view

Michael Sundler

Telectronics Ltd, London NW9 representing the UK branch of the international association of pacemaker manufacturers on the manufacturers' view.

Richard Sutton

Westminster Hospital, London SW1 on the aims of the pacemaker clinic and medical and technical competence. [now Royal Brompton Hospital]

David Ward

St George's Hospital, London SW17 on indications for referral to a specialist centre and telephone monitoring

John Worroll

MDA, London SE1 on recalls, advisories and traceability

following the presentation a discussion was held including the speakers and the attendees that formulated the recommendations.

the council of BPEG has subsequently acted as the writing committee. its members are: Richard Sutton, Anthony Nathan, John Perrins, John Camm, Anthony Rickards, David Cunningham, Douglas Skehan, Janet McComb, Richard Charles and Ann Forrester

Appendix 2:

Addresses of the official bodies relevant to pacemaker follow-up

British Pacing and Electrophysiology Group 9 Fitzroy Square London W1P 5AH
tel: 0171-717-1578 fax: 0171-717-1574

National Pacemaker Database (NPDB) Royal Brompton Hospital Sydney Street
London SW3 6NP tel: 0171 - 351 - 8736

Department of Health Medical Devices Agency and Adverse Incident Centre
Hannibal House London SE1 tel: 0171-972-8080