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GUIDELINES FOR PACEMAKER FOLLOW UP

Report of a British Pacing and Electrophysiology Group (BPEG) policy conference on pacemaker follow up: prepared by Richard Sutton for policy conference participants and BPEG Council

Follow up is a vital part of pacemaker treatment which demands staff training and experience and equipment availability. For patient benefit the requirements for pacemaker follow up need to be defined as accurately as possible and applied to the present UK health care system. The definition of these requirements was addressed by a policy conference conducted by the British Pacing and Electrophysiology Group (BPEG) on 14 January 1993. During the same year the North American Society of Pacing and Electrophysiology (NASPE) also held a policy conference on pacemaker follow up.[1] The BPEG conference was attended by speakers and delegates drawn from all kinds of pacemaker practice in the UK (appendix 1). Its recommendations are presented here and provide a logical next step beyond BPEG's recommendations for pacemaker prescription for symptomatic bradycardia.[2]

Present situation

Pacemaker follow up is of a very high standard in some centres in the UK. Basic follow up is widely conducted in the UK but in some instances it is with minimal facilities, technical knowledge, skill, and medical input: a few districts have no follow up service. 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 a hand-held electronic monitor to measure stimulus-stimulus interval and pulse duration. Records are sometimes rudimentary. Some follow up clinics have access to simple devices for waveform analysis and keep in close touch with a major centre by telephone or fax. A few follow up clinics provide a small number of home visits for immobile patients.

Immediate future

The programmability and increasing complexity of pacemakers will impinge on follow up at all levels. Programming should always be the responsibility of the supervising physician. Often it is performed by a cardiac technician supervised by a physician, but the physician or the technician or both may lack the necessary experience. Programmers for the full range of generators under follow up are not always available.

Since 1991, when the new British health care system was introduced, the number of pacemaker centres has increased and further increases are expected. There is concern over the lack of a national policy for the development of pacemaker services and the human and technical resources that are necessary remain to be determined. The price of pacemakers is much lower in the UK than in other western countries and does not allow manufacturers to give more support to small clinics. An increase in the number of clinics will dilute resources and as a result manufacturers may be forced to consider measures such as the sale or lease of programmers (presently provided free in most instances) and charging for advice by their technical staff. 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

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 treatment to permit prompt treatment.
(3) Prediction of end-of-life of the pulse generator 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 as possible (including a link to the NPDB).
(6) Provision of training opportunities for medical and paramedical staff.
(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 on clinics

Mandatory:
Resuscitation equipment
Multichannel electrocardiograph
Magnet
Relevant range of pacemaker programmers (for devices in use in that centre)
Manuals for all relevant pacemaker and programmers
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
Contact telephone numbers of all relevant manufacturers or their UK agencies
File of Department of Health Pacemaker Technical Notes and notices from manufacturers
Access to *x* ray facilities, exercise testing, 24 hour ambulatory electrocardiography
24 hour telephone answering facilities manned by competent staff
Access to temporary pacing facilities (chest wall, transoesophageal and/or transvenous)
Facilities to admit patients as emergencies at any time
Recommended:
Electrocardiographic screen monitoring
Equipment for pulse waveform analysis; a dedicated device with or without a measuring oscilloscope
Computer for patient database with modem link to the NPDB
External pacemaker and electrodes to provide chest wall stimulation for implanted pacemaker inhibition
Reference medical and technical textbooks
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.
Symptoms.
Skin overlying the pacemaker system.
(B) > 12 s Multichannel 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. Acquisition of generator telemetry concerning lead functions 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) Cross-talk evaluation and susceptability 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.

General Hospital (DGH) level with close cooperation, where appropriate, between the DGH and the 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.[3 4]

Functional aspects of a pacemaker clinic

Accurate record keeping is of the utmost importance. An implant report, discharge summary, previous follow up notes, medical letters, and the pacemaker's program should be available to the clinic. Files should be created in the database for procedures, generators, and leads so that, in the event of an advisory or recall, patients can be more easily traced. 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. This is aided by the British Heart Foundation booklet on pacemakers,[5] the manufacturer's literature, and any that is locally available. Before hospital discharge, patients should be given the European pacemaker registration card and 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 repeat 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, in a comprehensible manner, all doctors caring for each patient. Those not trained in pacemaker medicine will not understand jargon. Patients who do not 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 manufacturer(s) of the generator and lead should also be informed.

Any documented or suspected malfunction of a generator or lead 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 the 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 if sufficient human and equipment resources are made available to them. It is expected that these cardiologists will have arrangements with a nearby cardiac surgical centre to undertake procedures 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. Further cooperation between a DGH unit and pacemaker centre includes, for example, a visiting cardiologist to perform procedures or to do a follow up clinic (with the patient attending the unit clinic and the pacemaker centre's clinic alternately) or the provision by the centre of a mobile clinic with staff and equipment to visit the unit. The aim is to deliver the best possible local service for pacemaker patients, who 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. 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.

Patients should attend a pacemaker centre for follow up if the DGH lacks medical expertise or technical equipment (for example, programmers and tilt testing), if there are no trained technicians, or the DGH unit is unable 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 is not much used in the UK despite its technical feasibility but it is of value for partial follow up for the very disabled and for those who live a long way 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 1 January 1995. There is now a statutory obligation for manufacturers to report adverse incidents to the Competent Authority, which in the UK is the Medical Device Agency (MDA) of the

Department of Health. Though the onus to report now falls on the manufacturer the system will function only if clinicians take the initiative to report to both 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 obligation for manufacturers to report. 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 or modification or withdrawal of a device. When any advisory is issued it is important that all implanting and follow up centres are informed because patients may have moved from one centre to another. Pacemaker centres and follow up clinics will receive three communications in such an event: one from the manufacturer, the second from the MDA, and a third from the NPDB (with clincial advice where appropriate from BPEG) which holds the patients' 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 are responsible for 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 plans to establish a core curriculum which is taught by the group 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 examination of the North American Society of Pacing and Electrophysiology (NASPEXAM). At present there is no British equivalent of this examination. The North American Society holds separate annual examinations for physicians and technicians. The courses above that are planned in the UK expect to offer updating with continuing medical education credits. There are opportunities for continuing medical education for both physicians and technicians in the UK at the BPEG and British Cardiac Society Annual General Meetings and at international meetings. There are two peer review journals—*Pacing and Clinical Electrophysiology* published in the USA and the *European Journal of Cardiac Pacing and Electrophysiology* published in Munich, Germany—as well as articles in other medical and cardiological journals.

Staffing, skill, and training levels and quality control

The recommendations of the policy conference are given in table 5.

The migratory patient

Follow up of patients with pacemakers who move home should be transferred to a local centre. The transfer of follow up should be made with the cooperation of the implanting (and previous follow up) centre. The implications are that the new clinic takes over responsibility for ensuring that the patient remains traceable and that copies of the patient records are transferred.

Table 5 Skill training and competence in pacemaker follow up

*Level 1 Follow up at non-implanting centres**
Medical staff—One cardiologist with an interest in and training in pacing.
Technical staff—One technician minimum grade MTO2.[6]
Training—Technician has attended an approved course on pacing.
Quality control—Monitored by cardiologist with involvement of the implanting centre when appropriate.
Audit.
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. One member of junior staff training.
Technical staff—Two technicians minimum grade MTO2.
Training—As for level 1 for both technicians.
Quality control—Maintained by lead consultant of the unit and by audit.
Equipment—As for level 1.
Level 3 Follow up at specialist pacemaker centres†
Medical staff—Two cardiologists with an interest in pacing. One or more members of junior staff in training.
Training—As for level 1 for all technicians.
Quality control—As for level 2.
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.

Conclusion

The recommendations of the policy conference are expected to improve care, at all levels, of patients with pacemakers. These recommendations emphasise close cooperation between the physician, technician, and the centre responsible for care of patients with pacemakers.

Appendix 1

Invited participants at the BPEG pacemaker follow up conference under the chairmanship of Richard Sutton

Roger Blackwood, Wexham Park Hospital, Slough, Bucks: on basic follow up, the DGH view, and medical and technical competence. Ann Ingram, Westminster Hospital, London SW1 (now Royal Brompton Hospital): on technical equipment and record keeping. 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 (now Royal Brompton Hospital): on the aims of the pacemaker clinic and medical and technical competence. 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 who formulated the recommendations. The council of BPEG has subsequently acted as the writing committee. Its members were: Richard Sutton, Anthony Nathan, John Perrins, John Camm, Anthony Rickards, David Cunningham, Douglas Skehan, Janet McComb, Richard Charles, Ann Forrester, Suzanne Ludgate, Peter Solesbury, Michael Sundler.

Appendix 2

Addresses of the official bodies relevant to pacemaker follow up

British Pacing and Electrophysiology Group, c/o British Cardiac Society, 9 Fitzroy Square, London W1N 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, Elephant and Castle, London SE1 6TQ. Tel: 0171-972-8080.

1 Bernstein AD, Irwin ME, Parsonnet V, Wilkoff BL, Black WR, Buckingham TA, *et al.* Report of the NASPE policy conference on antibradycardia pacemaker follow-up: effectiveness, needs, and resources. *PACE* 1994; 7:1714–29.
2 Clark M, Sutton R, Ward D, Camm AJ, Rickards A, Ingram A, *et al.* Recommendations for pacemaker prescription for symptomatic bradycardia. *Br Heart J* 1991;66:185–91.
3 Furman S, Hayes DL, Holmes DR Jr. *A practice of cardiac pacing.* Armonk, New York: Futura, 1993.
4 Sutton R, Bourgeois I. The foundations of cardiac pacing: an illustrated practical guide. Armonk, New York: Futura, 1991.
5 Heart Information Series. No 9. *Pacemakers.* London: British Heart Foundation, 1990.
6 Definitions of medical and technical officer (MTO) competency and training levels. Department of Health.