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SPECIAL REPORT

Report of the Policy Conference on Pacemaker Reuse Sponsored by the North American Society of Pacing and Electrophysiology*

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Today's health care economy requires that methods be found to maintain the quality of patient care while assuring the availability of costly new therapeutic devices within the constraints of an increasingly limited budget. Reuse of cardiac pacemaker pulse generators may be one way to help achieve this objective by allowing maximal utilization of such long-lived medical devices.

A recent survey of the North American Society of Pacing and Electrophysiology (NASPE) membership by Hauser (1) has shown that present cost-cutting measures instituted by hospitals across the United States in response to prospective payment systems (DRGs) are resulting in important changes in pacemaker implantation practices. This survey revealed that 45% of respondents were implanting less expensive pacemakers and 41% had adopted stricter criteria for selecting dual-chamber pacemakers. Thirty-eight percent avoided "nonessential features" in the pulse generators, 32% used a limited number of models and 27% indicated that they implanted fewer pulse generators altogether. Some small community hospitals and large teaching medical centers have been forced to curtail or discontinue pacemaker implantation (Boal BH, personal communication). Such trends already may have compromised the quality of medical care being provided to patients who require implantation of cardiac pacemakers.

To address these issues, a NASPE Policy Conference was held on September 21, 1984 to study the feasibility of reusing cardiac pacemakers that are still reliable and have many years of useful life remaining. The proceedings of this conference are being published elsewhere (2) and provide the necessary background for the conclusions presented here.

*The Policy Conference, sponsored by the North American Society of Pacing and Electrophysiology, 13 Eaton Court, Wellesley Hills, Massachusetts 02181, was held on September 21, 1984 in Queens, New York. This report is being published simultaneously in *PACE*.

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Experience with reutilization of cardiac pacemakers. Since 1978, there have been reports (3–8) from many parts of the world of safe and effective reuse of cardiac pacemakers after simple in-house cleansing, testing and sterilization. These data describe the efficacious reuse of almost 2,000 cardiac pacemakers and confirm the absence of mortality and increased morbidity caused by infection, rejection and hepatitis attributable to pacemaker reutilization. In this entire experience, there has been only one instance (9) of premature pulse generator failure ($< 0.1\%$ incidence) which could be attributable to reuse. This incidence compares favorably with past experience with new cardiac pacemakers. It should be noted that it is current medical practice to reuse other medical devices, such as renal dialyzers (10) or Sones and multi-electrode catheters, that were intended originally for single use. Previous economic circumstances led to disposal of such medical devices after single use because at that time and in those specific instances, it was less costly than cleansing and resterilization. Current economic realities justify consideration of the reuse of many of these "single-use" medical devices, including cardiac pacemakers.

The reutilization of cardiac pacemakers is fiscally sound. In a 1980 report from Melbourne, Australia, Mond et al. (4) estimated that because of the negligible cost of in-house refurbishing, almost the entire cost of each reused implanted pulse generator could be saved. This conclusion has been reinforced by reports from several other centers as well (5–7). It is clear that the cost of preparing a pulse generator in a hospital is only a small fraction of the cost of a comparable new pulse generator. The cost of having pulse generators refurbished by an independent agency or original manufacturer may differ.

Thus, the world experience indicates that the reuse of cardiac pulse generators is medically efficacious and safe if they are properly cleansed, sterilized, reliably tested for function and battery life and the use of the particular pulse

generator is individualized to a patient's needs as is the current practice with the variety of new pacemakers that are available. If these requirements are met, it is accepted that there are no medical contraindications to the interchangeable use of new or previously implanted pulse generators. To assess on an ongoing basis the results of such potential reuse of implantable pulse generators in the United States, the establishment of a registry of such devices is essential.

Suggested changes in regulations and legal policy. There are major constraints to pacemaker reuse, particularly the reluctance of a physician to recommend and the patient to accept a "second-hand" device, and the danger to the physician, hospital and manufacturer of legal liability in the event of device malfunction. Several changes in regulations (and eventually in perception) are recommended that may modify or obviate these objections.

Ownership of the pacemaker should be redefined. The pacemaker should be in the exclusive custody of the patient during that patient's need, then should become available for reuse when it has been explanted for any reason. Each candidate for a reused pacemaker must be informed that it has been used previously and also be informed of the risks, benefits, alternatives and possible incentives attached to acceptance of a previously used device. A conventional manufacturer's warranty should end with a *second* use unless otherwise stated. Nevertheless, the responsibility for quality of design and manufacture should continue with the manufacturer throughout the lifetime of the pacemaker.

The implantation of a previously used pacemaker should not be considered substandard care. Physicians should be allowed to reuse pacemakers in an individual practice under their sole responsibility in accordance with methods for evaluation and preparation of the pulse generator described later in this report. Hospitals should establish protocols for the intrahospital reuse of pulse generators by members of their medical staff within their institutional guildelines. In such cases of intrahospital reuse, the physicians who provide the subsequent use need not be the original implanters. The procedures described in this paragraph should be considered "physician practice" and, therefore, are not subject to regulation by the Food and Drug Administration. In such cases, the responsibility for knowledge of changes in pacemaker status after reuse belongs to the reusing physician or the institution. Reregistration with the manufacturer after implantation will ensure that the appropriate physician can be notified in the event of such a change in status. Once a pacemaker intended for reuse goes beyond the individual physician or institutional boundaries, it should be regulated as a manufactured product by the Food and Drug Administration. Necessary laws, regulations and policies should be developed to implement all of these recommendations.

Recommended guidelines for in-hospital reconditioning of pacemakers. With the understanding that reutilization will never be possible unless the legal issues have been resolved first, the following are guidelines recommended for *in-hospital reconditioning only*, with the anticipation that should reconditioning be done by the manufacturer or some other agency, it will be under their own individual standards and guidelines.

Any lithium or nuclear powered pulse generator should be considered acceptable for reuse except for the following: 1) any model with a questionable history, such as one that has been subject to recall or one with an actuarial survival at 1 year of less than 98% with confidence limits of 5% (data for pulse generator survival can be acquired from an independent national registry); 2) any pulse generator for which insufficient information is available from the manufacturer on which the interpretation of test results may be based (for example, battery impedance and normal direct current capacitor leakage); 3) any pulse generator whose *postexplantation* history cannot be documented by the responsible physician; 4) any pulse generator with significant physical defects of the case or the header; 5) any pulse generator explanted from a patient who was subjected to therapeutic ionizing radiation or defibrillatory shocks; and 6) any pulse generator in which the projected remaining useful lifetime is less than 5 years at nominal operating parameter settings.

In evaluating an explanted pulse generator for possible reuse, the specific tests to be performed will depend on the model being reprocessed. All appropriate noninvasive tests should be performed that might reasonably be expected to expose a defect. These include but are not limited to estimation of the residual useful battery capacity and assessment of device performance related to output, sensing, timing and logic, programmability and telemetry. The pulse generator should be subjected to vibration tests for the detection of potential intermittent mechanical problems.

Cleansing and sterilization are of utmost importance. Immediately after explantation, the pulse generator should be washed to remove blood and tissue debris. All movable parts, such as setscrews, plugs and O-rings, should be removed. After this washing, the unit should be soaked in an antiseptic solution. It should then undergo physical cleansing with detergents and other agents such as formaldehyde or gluteraldehyde. Finally, it should be packaged and sterilized, preferably with ethylene oxide according to accepted hospital protocol. All tests, cleansing and sterilization must be performed according to written protocols by skilled personnel who are trained in the appropriate techniques. Thorough records must be kept, with copies of these records placed on the patient's chart and in a central file.

In summary, this report supports the concept that the reuse of selected cardiac pulse generators is medically safe and efficacious. It is estimated that 20% or more of implanted pacemakers could be reused if this policy were adopted (4–8). It is urged that legal and technical criteria be established to remove the impediments to the adoption of this

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practice as a means of improving the cost-efficiency of the health care delivery system and reversing trends and practices that may compromise the quality of medical care.

References

1. Hauser R. Survey of attitudes toward the re-use of cardiac pacemakers in the United States. In: Clinical Progress in Pacing and Electrophysiology. New York: Futura (in press).
2. Proceedings of the NASPE Policy Conference on Pacemaker Re-Use. In: Ref 1.
3. Havia T, Schuller H. The re-use of previously implanted pacemakers. Scand J Thorac Cardiovasc Surg 1978;(suppl)22:33–4.
4. Mond H, Tartaglia S, Cole A, Sloman G. The refurbished pulse generator. PACE 1980;3:311–7.
5. Schaedel H, Schrier R, Precht H, Weber D. The re-use of explanted cardiac pacemakers—late results (abstr). PACE 1981;4:A-72.
6. Kovacs P, Gomory A, Worum F, et al. Five year experience with re-used pacemakers (abstr). PACE 1981;4:A-54.
7. Amikam S, Feldman S, Boal B, Riss E, Neufeld H. Long-term follow-up of patients with re-used implanted pacemakers. In: Steinbach K, Glogan D, Laszkovics A, Scheibelhofer W, Weber H, eds. Cardiac Pacing. Proceedings of the VIIth World Symposium on Cardiac Pacing. Germany: Steinkopff-Verlag-Darmstadt, 1983:491–3.
8. Kruse I. Experience from the re-use of implantable pulse generators. In: Ref 1.
9. Boal B. A review of published world experience in pacemaker re-use. In: Ref 1.
10. Sadler J. Re-use in nephrology (hemodialysis)–a model for device re-use? In: Ref 1.