

Issues affecting refurbishment and re-use of pacemakers

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ABSTRACT

This paper discusses the problems associated with the refurbishing and re-use of medical devices which are sold by manufacturers as 'single use items' by focusing in particular on the re-use of pacemakers. Re-use of single-use devices such as pacemakers does occur in Australia, and in many other parts of the world, but there has been little public awareness of this fact. The paper explains and discusses medical, legal and ethical issues which arise through the re-use of pacemakers. It also discusses the recommendations of the 1995 'Draft report of the NHMRC Expert Panel on Re-Use of Medical Devices Labelled as Single Use'.

Introduction

Over the past 30 years the use of more and more 'disposable' items of medical equipment such as needles and tubing has become common. Hospitals have considered re-using some of the expensive items, particularly if it is safe and relatively easy to wash and sterilise them for re-use, either for the same patient or for different patients. This re-use occurs despite the fact that they may be clearly labelled by the manufacturer 'for single use only'. *The Statement of Industry Policy on the Reuse of Single-Use Medical Devices*, issued by the Medical Industry Association of Australia Inc. in 1994, defines 'single-use' medical devices as 'those designed, tested, manufactured, labelled, use medical device after patient use and subsequent cleaning, disinfection or sterilisation, repackaging, and use on the same or another patient'.

Re-use of such single-use items raises important ethical and legal issues. This paper looks at a particular example of a single-use medical device – the pacemaker. Cardiac pacemakers are sold as single-use medical devices. As a result of infection, death from cardiac or non-cardiac causes, or other changes in a patient's cardiac situation, cardiac pacemakers are sometimes removed while they are capable of functioning normally for many more years. For some years, in Australia and overseas, cardiac pacemakers have been harvested, cleaned, sterilised, tested and re-used, a procedure referred to as 'refurbishing' (Mond et al. 1980). The purpose of this article is to discuss the issues associated with the re-use of pacemakers.

Put simply, cardiac pacemakers are electronic devices which are implanted under the patient's skin and attached to the heart with insulated wire leads. They are used mostly for patients whose hearts beat too slowly or would stop beating completely if they were not stimulated electrically. These devices can prolong life and often improve its quality.

The term 'pacemaker' is used to describe an integrated electrical system comprising a pulse generator and a lead. The remainder of the circuit consists of living tissue. A pacemaker lead is composed of a metal conductor covered with an insulator. Most pacemaker leads are implanted via veins and make contact with the inner lining of the right heart. Once the lead has been implanted, it is gradually incorporated into the tissues, making it virtually impossible to remove without extensive damage, particularly to the insulation. Only the pulse generator is suitable for harvesting, cleaning, re-sterilisation and re-use.

Modern new pacemakers may last from between 5 to 15 years. Generally, pacemakers which have been in use for over two years are not re-used.

NHMRC draft report on re-use of single-use items

Currently there does not appear to be any regulations or standards governing the re-use of single-use items in Australia. The *Therapeutic Goods Act 1989* (Cwlth) does not cover or specifically address the problem. It does cover manufacturing of medical devices, requiring manufacturers to comply with relevant codes such as the *Code of Good Manufacturing Practice for Sterile Medical Devices* issued by the Therapeutic Goods Administration in 1986. In turn, that code covers 'reprocessing' of medical devices in Clause 6.5, but the term is defined as 'the cleaning and re-sterilisation of

items where the package has been opened and the contents possibly contaminated, but not used on a patient', and does not really cover re-use of items.

A new Australian Standard, AS 4187-1994 – *Code of Practice for Cleaning, Disinfecting and Sterilising of Reusable Medical and Surgical Instruments and Equipment, and Maintenance of Associated Environments in Health Care Facilities*, was introduced in 1994. This standard specifically states in Clause 1.3.15 that it does not apply to items 'designated or intended by the manufacturer for single use only'.

However, the concerns about the risk of spreading infectious diseases, such as HIV and hepatitis B, have focused attention recently on the sterilisation and re-use of therapeutic goods. In July 1994 the Therapeutic Goods Group of the Commonwealth Department of Human Services and Health prepared a statement on the re-use of single-use devices, covering the safety of re-use practices, the ethical and legal issues which they raise, and the extent of any possible financial savings which may result from them, for discussion by the National Health and Medical Research Council later in the year (Therapeutic Devices Branch 1994). An expert panel under the National Health Advisory Committee, an advisory arm of the National Health and Medical Research Council, was then established in August 1994 to investigate the extent of re-use practices.

A draft report on the re-use of single-use medical devices was issued on 26 October 1995 by the panel (National Health and Medical Research Council 1995). The panel released the report for public consultation and anticipates releasing its final report in 1996. The draft report is concerned primarily with the re-use of single-use items, that is, where an item has been used on a patient, cleaned, disinfected, packaged and sterilised for re-use on another patient, rather than re-processing or re-sterilisation of items which have not been used previously on patients.

The draft report noted that the stated government policy on re-use of single-use medical items in Australia and in other countries has been to devolve responsibility for re-use to medical institutions while cautioning strongly against the practice. A survey of State and Territory government views conducted by the expert panel revealed that, although five of the States and the Australian Capital Territory strongly opposed re-use, the practice was widespread, mainly because of the perceived cost-benefits to institutions.

The report also found that data on the extent of re-use of medical devices did not exist. A survey of 12 major hospitals, both public and private, was commissioned to help determine the extent of the practice, the policies on re-use adopted by each institution, and the types of devices which were being re-used. The responses to the survey revealed that medical devices labelled as single-use items were being re-used or re-processed in all of the hospitals surveyed, yet only one of the hospitals had adopted a systematic approach to the practice, involving formal applications to re-use items, evaluation of the items, registration of the event and a review process. Most of the hospitals, however, had formal policies governing re-use and reprocessing of single-use medical devices. The survey also led to an impression that the quality control measures undertaken in respect of the cleaning, sterilising, packaging and storage practices were generally sub-standard (p 19).

It was noted that less re-use of single-use items had occurred over the last 18 months, apparently as a result of medico-legal consequences rather than because of concerns associated with re-use practices.

The expert panel considered that the current practice of re-use could not be condoned, due to problems with the lack of adequate hospital processing or quality control standards. It went on to accept, however, that the re-use of expensive single-use items such as electrophysiological catheters could be justified on cost-benefit grounds. Re-use of less expensive items could not be justified so easily. The expert panel also expressed concern that the issue of patient consent for re-use of single-use items was not adequately addressed by standard patient consent forms used in hospitals.

Fourteen recommendations are contained in the draft report, grouped into the following areas:

(a) Decision on re-use and provision of funding

Australian health ministers should either clearly state that single-use items should not be re-used and introduce ways to enforce this decision *or* re-use should be allowed to continue but should be subject to more stringent regulation.

(b) General recommendations on sterilisation practice

All sterile supply services should meet Australian Standard AS 4187-1994, whether or not single-use and disposable devices are involved.

(c) Re-use of medical devices labelled as single-use

Medical institutions seeking to process devices for re-use should be licensed and must comply with national standards, including a cost-benefit appraisal of the re-use of each device, informed consent procedures for patients and maintenance of a register.

(d) Further research

A national outcomes study on the re-use of single-use devices should be undertaken by the National Health and Medical Research Council.

Problems of pacemaker re-use

Pacemakers are sold as single-use products. As mentioned earlier, while the leads are clearly unable to be re-used, the pulse generator can and has been re-used. It has been argued that there are few risks associated with pacemaker implantations, the main ones being system malfunction and infection (Mond et al. 1980; Conseil d'évaluation des technologies de la santé 1991). The question explored below is whether the risks associated with using refurbished pacemakers are greater than those associated with new pacemakers. The fact that there are risks with new pacemakers was clearly demonstrated by the recent case of the faulty leads manufactured by Telectronic (Sproull 1995).

Malfunction

Pacemakers can malfunction at any stage during their use. Records of initial pacemaker use are kept by manufacturers and, supposedly, by hospitals. A pacemaker will only be considered for re-use by a hospital if it has no record of malfunction and has been in use for less than two years. An estimate is made of the future life of the battery and of the expected working life of the particular pacemaker model. A pacemaker will not be re-used if it was harvested from a patient who died suddenly and malfunction of the pacemaker cannot be totally ruled out by the hospital as a cause of death or if its history after removal from a patient is not documented (Conseil d'évaluation des technologies de la santé 1991).

The battery life of a refurbished pacemaker will be shorter because of its prior use. But there is no evidence to show that a pacemaker which

has only functioned for a short time and which is then re-used is more or less likely to malfunction because of that re-use.

There may be a risk to a patient if a refurbished pulse generator is improperly selected for re-use due to an inaccurate history of use. Ideally, a record of re-used pulse generators should be kept and maintained. A national register system would enable the identification of all seemingly normal pulse generator explants and their recertification (Sutton 1994). At this stage, hospitals keep their own records of refurbished devices and, as revealed in the survey of hospitals undertaken for the National Health and Medical Research Council expert panel, these records can vary as to accuracy and content.

If pacemakers are to be re-used, the original manufacturers should refurbish their own instruments. However, no manufacturers in Australia will provide the service, although manufacturer refurbishment does occur in other countries (Conseil d'évaluation des technologies de la santé 1991). Pulse generators therefore have to be refurbished in-house by the institution which contemplates their re-use.

Infection

Sterilisation and the complete removal of all protein material are two important problems that relate to the re-use of pacemakers (Greatbatch 1985). Improper cleaning or re-sterilisation of previously implanted pulse generators can cause secondary infections. New cardiac pacemakers can also in rare instances become infected and have to be removed because they are no longer sterile.

The problem of effective and thorough cleansing and whether it is possible or practical depends largely on the pulse generator design. If the device has plastic components there may be deeply penetrating interfaces as well as the possibility of cracking or crazing of the plastic, both rendering the device difficult to clean. Certainly the concern about viruses such as hepatitis, Creutzfeld-Jakob disease, HIV, and the possible viral aetiology of Alzheimer's disease is, of course, real but there is an absence of any data on the transmission (or lack of transmission) of infections associated with pacemaker re-use. The recent findings of the expert panel do indicate that, in many instances, standards of reprocessing of single-use items were poor and varied from hospital to hospital (National Health and Medical Research Council 1995).

In the 1980s it was reported that the incidence of infections and other complications with re-used pulse generators was the same as that observed with brand new units (Mond et al. 1980). More recent data, however, have been hard to locate. Re-use of cardiac pacemakers has been conducted successfully in many countries for over 30 years now. At a Policy Conference of the North American Society of Pacing and Electrophysiology held in Washington DC in 1984, on the re-use of cardiac pacemakers it was concluded that ‘...the re-use of cardiac pulse generators is medically efficacious and safe if they are properly cleansed, sterilised, reliably tested for function and battery life and the use of the particular pulse generator is individualized to a patient’s needs...’ (Conseil d’évaluation des technologies de la santé 1991). Countries like Canada, Sweden, Switzerland, India, Israel and France allow pacemakers to be re-used. In some countries, like the United States, re-use of pacemakers is not permitted although export of refurbished pulse generators may be allowed (Rahmoeller 1985; Conseil d’évaluation des technologies de la santé 1991). In other countries, like Australia, there has been little awareness of the practice and thus little discussion of the issues. Some countries, such as the United Kingdom, ban re-use (Sutton 1994).

Legal implications

There are a number of legal problems associated with the re-use of single-use items, including concerns about the need for government standards, patient rights, product liability, and device registers. These problems are discussed below.

The main legal concerns associated with the re-use of single-use items arise when a patient has suffered an injury or has died, and the re-used item appears to be linked with that injury or death. As discussed earlier, the risks associated with re-use of pacemakers involve malfunctions and infections. A patient or their representative may argue, for example, that there was negligence on the part of the hospital, the surgeon and others involved in the refurbishing. If not an employee of the hospital, the surgeon may be sued separately.

In the event of a patient or a patient’s representative suing a hospital and a surgeon for injury or death arising from the use of a refurbished pulse generator, the hospital’s insurers defending the claim have only two concerns. First, has the unit been used in accordance with the

manufacturer's instructions and specifications and, second, did the patient give informed consent to the use of a refurbished device?

Negligence

Negligence is an action arising under the law of tort in which it is claimed that there was a failure by one person to exercise due care with the result that another person suffered injury or damage because of that lack of care. In the case of a patient with an implanted refurbished pulse generator, he or she would have to show that the hospital and its staff had failed in its duty to him or her in some way. Grounds for arguing such failure in the event of infection or malfunction could include:

- failing to properly refurbish the pacemaker, leading to infection
- failing to advise that the unit had been refurbished as the patient would not have proceeded with the operation had he or she known, or
- implanting a defective unit or one that subsequently becomes defective.

To prove that negligence occurred, the patient plaintiff would have to show that the hospital/surgeon owed a duty of care to him or her, that this duty was breached, and that injury was suffered by him or her as a result of this breach. The injury suffered by the plaintiff must have been foreseeable by the defendants, hospital, surgeon and staff (Bates & Dewdney 1988). In respect of the three grounds mentioned above, it is foreseeable that injury could result if a unit was improperly refurbished, resulting in infection or malfunction, or if the battery life of the device had been substantially reduced through prior use. The fact that the hospital had ignored the manufacturer's instructions as to the single use of the device or had ignored government or even the hospital's own prohibitions against such re-use would be important factors supporting a claim of negligence.

Product liability

In Australia, manufacturers of pacemakers will not refurbish these devices. All of the new cardiac pacemakers have a lifetime warranty against electronic defects but the sale contracts of major manufacturers and importers provide that this warranty becomes invalid if the pacemakers are re-used. The view of the manufacturers, apparently, is not that the

pacemakers cannot be refurbished safely but that they are not prepared to be liable for damages which may arise from the re-use of the units. Generally, manufacturers and importers of pacemakers will not be responsible for any direct or consequential damages or expenses resulting from the cleaning or re-use of the equipment.

This means, therefore, that the hospital will be solely responsible for any damages payable as a result of injury or death arising from the refurbishment of the pacemaker where that injury or death was the result of failure to sterilise or clean the device properly, or where the device had a dubious history in that, for example, the cause of death of its previous recipient was not clear.

Normally, if a product such as a pacemaker is defective, then the manufacturer will be liable. However, in the case of a refurbished unit, the manufacturers will argue that they are no longer liable and that the hospital has assumed its position as manufacturer and its liability for defective products. Product liability in Australia is covered by the law of negligence, as discussed briefly above, and by the *Trade Practices Act 1974* (Cwlth) or similar State and Territory legislation.

Under Division 2A of the Trade Practices Act, a manufacturer is liable if goods injure a consumer or other person. The plaintiff has to prove that the goods supplied by the manufacturer were defective. Negligence does not have to be proved. If the original manufacturer cannot be located or is overseas, legal action can be taken against the retailer or importer, whichever is appropriate. In the case of a defective pacemaker, the patient has to show that it is defective. The question which then arises is: When did the defect occur?

Section 75AK of the Trade Practices Act provides a defence by which the manufacturer can claim that the defect did not exist when first supplied by the manufacturer, that is, it will not be responsible for later improper use. Pacemaker manufacturers clearly state that the devices are single-use items. A hospital which refurbishes a pacemaker therefore may be deemed to be the manufacturer and liable for defects.

Patient consent

The issue of informed patient consent is an important one. Patients must be in a position to give consent to any medical procedure carried out on them. They must have been provided with adequate information about their illness and the proposed treatment. They have a right to know about

any risks, however remote, involved in their treatment, as reinforced in the recent case of *Rogers v Whitaker* (1992) 109 ALR 625.

As discussed earlier, the observed incidence of infections and other complications appears to be the same in new and re-used units. Potential risks which could be linked directly to the re-use of a pacemaker, such as a greater exposure to infection if the unit has not been adequately sterilised, have not been clearly identified at this stage.

Patients should be advised that the surgeon proposes to use a refurbished pacemaker. They should also have the right to choose not to have the unit implanted, as long as they are fully aware also of any implications inherent in this decision. Failure on the part of the surgeon and hospital to advise the patient that a refurbished pacemaker was to be used could lead to a claim that the patient had not fully consented to the procedure. He or she may have consented to an operation but not to the use of the re-used pacemaker. To prove such a claim, action can be taken either under the law of negligence, already discussed above, or under sections 52 and 53 of the Trade Practices Act. Section 52 prohibits a corporation from engaging in conduct which is 'misleading or deceptive or is likely to mislead or deceive'. Failure to advise a patient that the medical device to be used in an operation has been used previously, although classified for single use only, could be deemed to be misleading or deceptive conduct. Section 53 prohibits corporations from making false and misleading statements about the supply of goods and services, including ones that imply that goods are new or of a certain standard or quality.

Ethical issues

In any health system in which some patients may be denied treatment because of lack of resources, any wastage must cause concern. To discard a used pacemaker, or any other single-use item, while it retains a greater part of its functional life is wasteful.

An operation for a pacemaker implant involves hospital, surgical and hardware fees. The cost of the pulse generator and the leads constitute almost 80 per cent of the total cost. A refurbished pacemaker, however, can involve reduced costs, particularly if the refurbishing is done in-house. There are therefore considerable cost savings which can be made by the health provider and the health system generally which could clearly justify the use of refurbished pacemakers, a finding reached by the National

Health and Medical Research Council expert panel in respect of expensive single-use devices.

As discussed earlier, there is no evidence to suggest that a refurbished pulse generator is less or more safe than one that is new. Important questions to ask, however, are which patients will receive a second-hand pulse generator, and who decides? At present the majority of recipients of refurbished pacemakers are very old, or very ill, or have a limited prognosis. Many of the patients, due to dementia, illness or language barriers, will have limited communication or understanding. Often the operation is done as an emergency. Where relatives are required to give consent for an operation, they normally do not consent to the use of a refurbished pulse generator. In this situation it is more than likely that the simplest and cheapest new pacing system is selected by the surgeon, rather than a more appropriate, but refurbished, one.

There are considerable financial savings for the hospital concerned and the health system generally if single-use items such as pulse generators are able to be re-used. The health system in every State and Territory in Australia is facing escalating costs and reduced funding and, provided that a patient has every guarantee of being supplied with just as reliable a pacemaker as a new model, there should be no reason to pass up these savings.

It is difficult to determine the potential savings which may result from pacemaker re-use. Reports from around the world suggest that between 1 per cent and 40 per cent of pacemakers are being re-used. In Quebec in 1990, a total of 2349 new pacemakers were implanted. In Australia, in 1989, approximately 2723 new pacemakers were implanted (Conseil d'évaluation des technologies de la santé 1991).

The National Health and Medical Research Council expert panel attempted to gather data on the savings which could result from reprocessing single-use items, using electrophysiological catheters as the basis for comparison. Apart from finding that some hospitals did not attempt any cost-benefit analysis of re-used items, it found that significant savings could be made, particularly if the re-processing was undertaken by a single national processing centre.

The decision to re-use cardiac pacemakers, and how they are to be re-used, is a decision made primarily by the hospital and the relevant physicians at present. There is no doubt that the motive for re-use is primarily one of saving costs. This is not automatically a bad motive; it should, in fact, be commended. The decision, however, should be made

openly by the hospital in accordance with national standards, and with the awareness and consent of patients.

Conclusion

Pulse generator re-use has been successfully reported in many countries over the last 25 years, and has been practised at some major Australian hospitals for over 20 years. If re-use of single-use items such as pacemakers is to be accepted, there must be a higher level of public awareness and acceptance, and better quality standards of the type recommended in the draft report of the National Health and Medical Research Council.

At present there are no formal protocols defining the procedures of re-utilisation of expensive single-use items. The principles guiding re-use and the precise protocols to be followed should be well defined and officially approved at a national level. A prior history of the item must be maintained and the actual costs of refurbishing must be known. High standards of cleaning, sterilisation and testing must be followed and a record of each step in the refurbishing maintained. Patient consent must be obtained. Follow-up procedures after implantation, such as monitoring and maintenance of a register, will need to parallel those used for new implants.

Re-use of single-use items has been occurring in Australian hospitals for many years but there has been little awareness of the practice outside the hospital environment, possibly because there was apprehension about the reaction of the public to such knowledge. It is ridiculous to continue the current double standard of governments and hospitals warning against a practice which is widespread. Now is the time to ensure that the appropriate re-use of items is justified and monitored. It may also be the time to query whether the designation by manufacturers of some items as single use only is appropriate.

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References

- Bates P & Dewdney J (eds) 1988, *Australian health and medical law reporter*, CCH Aust. Ltd, Sydney.
- Bernstein AD 1985, 'Electrical evaluation of pacemakers for reuse', *Clin Progress*, 3, pp 36–45.
- Brown MD 1985, 'Reuse of cardiac pacemakers: legal implications', *Clin Progress*, 3, pp 48–52.
- Conseil d'évaluation des technologies de la santé 1991, *The reuse of permanent cardiac pacemakers*, Canada Government, Quebec.
- Greatbatch W 1985, 'Considerations of the reuse of implantable prosthetics', *Clin Progress*, 3, pp 46–7.
- Medical Industry Association of Australia Inc. 1994, *The statement of industry policy on the reuse of single-use medical devices*, MIAA, NSW.
- Mond H, Tartaglia S, Cole A & Sloman G 1980, 'The refurbished pulse generator', *PACE*, 3, pp 311–17.
- National Health and Medical Research Council 1995, *Draft Report of the NHMRC Expert Panel on Re-Use of Medical Devices Labelled as Single Use*, National Health and Medical Research Council, Canberra.
- Parsonnet V & Bernstein AD 1991, 'The 1989 world survey of cardiac pacing', *PACE*, 14, pp 2073–6.
- Rahmoeller GA 1985, 'Reuse of pacemakers – The FDA's viewpoint', *Clin Progress*, 3, pp 42–5.
- Sproull R 1995, 'PacDun's anxious watch on problems with pacemakers', *Weekend Australian*, January 28–29, p 36.
- Sutton R 1994, 'The value of registers', *Eur JCPE*, 2, pp 79–80.
- Therapeutic Devices Branch 1994, 'Re-use and sterilisation of therapeutic devices', *Australian Therapeutic Device Bulletin*, 2, pp 1–12.