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Policy Document

Re-use of devices in cardiology

Proceedings from a Policy Conference at the European Heart House, 5–6 February, 1998

Introduction

The Committee for Scientific and Clinical Initiatives, with the approval of the Board of the European Society of Cardiology (ESC), has initiated Policy Conferences in the European Heart House. The purpose of such conferences is to provide a forum for debating matters of importance for the practice of cardiology. Subjects to be addressed are those where knowledge is still insufficient for the creation of an official ESC Task Force with a view to writing European practice guidelines[1]. Other subjects, which will be handled in the format of Policy Conferences, include those medical issues that have ethical, legal, industrial, administrative and political implications.

Each Policy Conference starts with an initial session comprising a series of lectures given by invited experts, including not only cardiologists but also specialists in technical, legal, ethical or political matters. The presentations are given before a group of invited panellists with substantial specific expertise and a group of attendees with broader based backgrounds. The experts' presentations and written documents are then considered by the panel members. The panel presents to the attendees a statement based on the presentations and, during a second session, these statements are debated by the attendees and the experts. The panellists make use of this input to finalize a Policy Document. Following ESC Board approval, the document will be published in the *European Heart Journal* and distributed to all who may have an interest in the subject. It is hoped that Policy Documents will serve as a platform to encourage research and support medical, legal, political and administrative decisions. Such Policy Documents should facilitate the writing of future European Guidelines designed to improve the provision of health care in the relevant area.

The first ESC Policy Conference was organized in the European Heart House, 5–6 February 1998, addressing the issue of Re-use of Devices in Cardiology. This article is the Policy Document from the conference.

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Background

The increasing cost of health care is a universal European problem. Many attempts have been made to decrease these costs, some initiated by the medical profession and others by politicians and administrators.

When cardiovascular diseases are considered specifically, many types of treatment, such as catheter-based coronary and electrophysiological interventions and the use of pacemakers, have improved longevity and quality of life for many patients. The costs of these devices are still high, even though some costs related to these technologies have decreased in recent years. Advances in techniques and methods of quality control should permit the safe re-use of some of these instruments which may contribute to the lowering of health care costs (see table in Dr C. Blomstrom-Lundqvist's paper in future supplement).

Within Europe and elsewhere the attitudes towards the re-use of devices in cardiology vary considerably. In some countries, re-use is prohibited by law, while it is practised in other countries with or without legal approval. Laws have not always been known or understood by the medical profession, or doctors have unwillingly not complied with these laws. This may partly relate to a lack of understanding of recent changes in the laws that regulate responsibilities and liabilities related to the re-use of *sterile devices labelled for single use only*. It is this equipment that is the focus of this document.

Objectives

Patient safety should be paramount in issues of this kind. The panellists reviewed published information on the re-use of devices. A synopsis of European laws and regulations in the field increased awareness of liability issues. Ethical aspects of the re-use of devices were also considered. With this information as a background the panellists issued recommendations for present practice. These are based on the assumption that safe re-use may continue under strict regulations and respect existing laws.

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Present practice

During the Policy Conference experiences with the re-use of pacemakers, defibrillators, catheters for invasive electrophysiology and for diagnostic and interventional purposes were summarized. Based on these presentations, present practice was summarized as below. The full presentations are available as a supplement to the *European Heart Journal*[2].

General issues

Ethics

The underlying ethical problems associated with the re-use of cardiologial devices can be considered within the conventional triangle of benefit, risk and cost. Other factors — including the law — may have an impact on the triangle. There are few reasons to believe that the benefit to a patient from a properly refurbished device will be any less than that to be expected from a new device. The central issue is the balance between possible attributable risks of refurbishing the re-used device and the possible advantages in terms of cost.

Closely related to this ethical standpoint is the question of responsibility, and who makes the relevant decisions. The patient would like these to be made solely on the basis of his/her welfare; all other parties have conflicts of interest. Doctors, hospital administrators, industry personnel, lawyers, and politicians all have differing conflicts; some conflicts are more apparent than others.

In an ideal world, the ethical decisions would be made easier by knowing the results of randomized controlled trials in which new devices are compared with re-used ones; the results of such trials would need to be combined with cost analysis. Any such trials could be performed under the auspices of the ESC.

Legal aspects

European Union countries

Throughout Europe there has been great variation of medical practices (sometimes supported by national laws) concerning the re-use of cardiological devices. In some countries (France, for example) the government policy is simple and unambiguous: there is no re-use. In Germany, on the other hand, the re-use of devices that are labelled for single use is *not* prohibited by law. The German Department of Health issued special regulations allowing this in July 1998. These specified that the persons or institutes processing medical devices should be technically qualified, have access to the appropriate equipment, and employ *validated* procedures (such as cleaning, disinfection and sterilization). A new CE mark does not need to be put on the reprocessed device, providing that it is not put on the market. Furthemore, the device must stay in the possession of the first user.

The European Union has now produced harmonized legislation — MDD/93/42/EEC and AIMD 90/385/EEC — which governs the regulations applicable to all medical devices placed on the EC market. This legislation is mandatory and came into force in June 1998. The purposes of the legislation is to ensure that all products placed on the market are consistently safe and perform to the specifications determined by the manufacturer. If the product complies with the directives above, the 'CE' mark is put on it. This mark is already present on many approved devices on sale throughout the EC, such as toys and television sets

The directives do not state whether the product should be for single use or re-use. This decision is made by the manufacturer, who indicates the intended purposes of the device on the appropriate label. There are three possible labels: the manufacturer may state that (1) the product is for single use and is sterile, or (2) the device is re-useable and sterile and provides appropriate information about re-use, or (3) the device is non-sterile and re-usable; the manufacturer provides the information needed to process the device before use (e.g. endoscopes). If the user of a single-use device, labelled as such by the manufacturer, wishes to re-use it (i.e. reprocess and resterilize it), the EU directives say that such re-use would render the re-processor a new manufacturer. In reprocessing the device, the user becomes subject to the same requirements of the directives as the original manufacturer. A new CE mark would need to be applied to the reprocessed device. Furthermore, all obligations of the manufacturer would fall to the reprocessor. These include tests for biocompatibility, sterility, quality control, documentation and traceability, and the reporting of adverse events.

Liability issues also arise if a re-used medical device causes damage or injury, for the reprocessor is likely to be held personally liable: criminal or civil liability may apply, depending on the EU member state.

Non-European Union Countries

In the case of non-EU countries, the law of the individual countries should be reviewed and respected. The laws of certain countries may be different today from the EU legislation. However, those countries which will eventually become EU members will be obliged to harmonize their laws accordingly.

Medical practice

When a patient gives informed consent for the use of a re-used device, it should be made clear to the patient that the device is re-used. Should a patient die with a medical device, such as a pacemaker, in his/her body, it may be necessary to obtain consent from the family of the deceased person to have the device explanted. The law as to the ownership of an implanted device varies from country to country; thus in Sweden a pacemaker is the property of the implanting centre and the pacemaker is required by law to be removed from the body before

cremation or burial, and such removal is not considered an autopsy. In the Netherlands the pacemaker is the property of the patient (or the patient's family).

Specific issues

(1) *Electrode catheters for temporary pacing and electrophysiological studies; ablation catheters*
Of the cardiological devices discussed here, these solid catheters represent the category of devices that have been most often successfully re-used, though the overall extent of re-use is unknown. There is virtually no evidence that their re-use has caused harm; even so, their long-term safety has never been properly proven. It is clear that when re-use of these catheters is formally undertaken, it must comply with the country's law and/or the EU directives outlined above. Re-use of ablation catheters is likely to pose greater problems than temporary pacing and electrophysiological diagnostic catheters. If adequate prospective data could be provided on the safety and efficacy of re-using temporary pacing and electrophysiological diagnostic catheters, a modification of the EU directive would be necessary to make it a lawful practice. A research protocol under the guidance of the ESC could facilitate this, provided that an ethically approved protocol is undertaken, and that when the trial is concluded, the law of the land is respected.
(2) *Interventional and diagnostic catheters*
The case for re-use of these catheters is very different to that of devices for electrophysiological studies. Catheters are usually hollow (with holes) and are more difficult to clean and sterilize. Furthermore, after refurbishment, these catheters lose some of their mechanical properties. Re-use of these interventional and diagnostic catheters is not generally recommended.
(3) *Pacemakers and Implantable Cardioverter-Defibrillators (ICDs)*
Pacemakers have a tradition of re-use, although the vast majority are not re-used. Reports on the re-use of pacemakers are available from Europe (France, Italy, Norway, Germany, Sweden and the Netherlands), North America (Canada and the United States) and Asia (India) where re-used devices have successfully been given to elderly patients whose life expectancy is less than that of the pacemaker. The only available figures on the national extent of pacemaker re-use originate from Sweden. During 1996, 5% of pacemakers were re-used devices, and there is no evidence that re-use has increased patient risk. It must be acknowledged, however, that none of the available reports had a prospective, randomized design. In countries outside the EU, provided the law permits, re-use of pacemakers may be considered, provided that their sterility, mechanical and electrical integrity can be ensured and operating procedures are respected. Re-used pacemakers should only be given to patients whose life expectancy is estimated to be less than that of the pacemaker.

The re-use of ICDs is a less practical proposition: sterility, mechanical and electrical integrity are all difficult to ensure in the re-used device. A case can be made for the re-use of ICDs in patients waiting for cardiac transplantation. In fact, the EU regulations make it very difficult for institutions to refurbish either of these devices, for reasons which are indicated above. However, if an institution can arrange with the original manufacturer to re-furbish the devices (and provide them with a new CE mark, or perhaps a CE mark of their own), there is no reason why re-use might not become medically and economically acceptable.

Conclusion

It is the hope of the ESC Board that this document will encourage further studies in this field. There are several aspects of the re-use of devices in cardiology that need further exploration, even though the EU law on single use sterile devices is unambiguous. It is also hoped that this document will encourage increased co-operation between the medical profession and industry in order to solve some of the complex issues that are related to safe re-use of devices. The document may also serve as a platform from which the appropriateness of present laws and regulations may be discussed between legislators, cardiologists, industrialists and health care providers with their legal advisers.

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References

[1] Ryden L, Breithardt G, Poole-Wilson P. Distribution of Knowledge. Eur Heart J 1997; 18: 1523—5.
[2] Re-use of devices in cardiology. Report from a Policy Conference at the European Heart House, 5–6 February 1998. Eur Heart J 1999; (Suppl in press).

Appendix

Policy conference at the European Heart House: 5–6 February 1998. The re-use of devices in cardiology

Speakers (5 February)
Chairman: Professor Lars Rydén (Stockholm, Sweden)
Michel Bertrand (Lille, France)
Michael Block (Münster, Germany)
Carina Blomström-Lundqvist (Uppsala, Sweden)
Gunter Breithardt (Münster, Germany)
Alan Howard (Brussels, Belgium) (Legal Adviser to ESC)
Cecilia Linde (Stockholm, Sweden)
Piotr Mierzewski (Strasbourg, France)

Detlef Nottebrock (Darmstadt, Germany)
Philip Poole-Wilson (London, UK)

Panellists (6 February)
Chairman: Kim Fox (London, U.K.)
Dennis Cokkinos (Athens, Greece)
Victoria Ann Dedrick (Brussels, Belgium)
Olof Edhag (Stockholm, Sweden)
Maarten Heyrmans (Maastricht, Netherlands)
Lars Rydén (Stockholm, Sweden)