SUMMARY

INTRODUCTION

Heart failure is common. Until recently, when medication was no longer able to maintain function, life could only be prolonged by cardiac transplantation. However, very few donor hearts are available each year.

Mechanical pumps have now been developed which can be implanted in the body of the recipient and take over the heart's function, thus prolonging life for months or years. These devices are being used in Europe and the USA but have only had very limited application in Canada and Quebec.

The present document reviews the available data pertaining to the decision whether they should now be used in Québec. It originally arose from a request by the *Régie régionale de la santé et des services sociaux de Montréal-Centre*; however, as the issue concerns the entire province, the *Ministère de la Santé et des Services sociaux du Québec* is very interested in the results of this evaluation.

Status of Technology

This is a new and rapidly developing technology but is no longer experimental. It is appropriate to consider it an "innovative" technology and as such, consider its application within the strict framework of data collection for research purposes.

Applications

Left ventricular assist devices (LVADs) are used in emergency situations where, in their absence, the outcome would be imminent death. They are also used electively in the context of progressive heart failure. LVADs may be used with three objectives: as a bridge to transplantation, as a bridge to recovery, or as a permanent alternative to transplantation.

Efficacy

The following estimates of outcome are no more than approximations, based on the results of the more recent reports:

Survival to transplantation or explantation can be expected for approximately 70% of implanted patients. In elective cases, prior LVAD use may improve *transplant* survival rates at 5 years from approximately 70% to possibly as high as 90%.

Hemorrhage requiring re-operation may occur in 20-44% of patients in the first few post-operative days, but is rare thereafter.

Thromboembolism rates have varied from 5-15% (HeartMate®) to 12-37% (Novacor®). The lower rates, 5% and 12%, are probably more pertinent to the present decision.

Infections, either systemic or local, are experienced by approximately 50% of patients. Both thromboembolism and infection are encountered throughout the duration of the implant but their frequency diminishes with time.

Quality of Life. Many patients on long-term LVAD support can return home and resume a near normal life, taking part in work and recreational activities. Overall, quality of life is superior to that of a patient in advanced heart failure but inferior to that of a transplant survivor.

Costs of implantation

The direct cost to the Canadian health care system of installing a Novacor® LVAD is approximately $138,000. Assuming 70% survival to transplant with an average 100 days support, this technology would increase the cost of each cardiac transplantation by approximately $200,000.

Cost-effectiveness

It is premature to attempt precise estimates of cost-effectiveness. First approximations based on hypothetical scenarios, considering only direct costs to the health care system, provide the following estimates:

- Bridge to transplant, *emergency interventions* for cardiogenic shock: No estimate possible. No additional lives saved.

- Bridge to transplant, *elective interventions* for patients awaiting transplantation: Estimates range from $91,000 to $126,000 ($117,000 to $186,000 discounted at 5%) per life year.

- Permanent alternative to transplantation. *Emergency use*: $52,000 (discounted: $50,000) to $60,000 (discounted: $58,000) per life year. *Elective use*: $71,000 (discounted: $68,000) per life year.

Economic Impact

If employed *strictly* as a bridge to transplant and so used before 10 transplant procedures per year, the total annual cost, exclusive of transplantation related costs, would be of the order of $1.4 million. Some implants will, however, become permanent, causing an increasing cost. If 4 of the 10 patients receiving LVADs remain on permanent LVAD support, the total cost, exclusive of transplantation costs, by the end of 12 years might be approximately $3.8 million per year. If used as a permanent substitute for transplantation for 1,500 patients each year, the annual expenditure after 12 years might be of the order of $570 million (while sustaining the lives of perhaps 9,500 patients).

Ethical and Social Considerations

Consideration of the ethical and social issues leads to the following tentative conclusions:

- It is no longer ethically acceptable to refuse all access to this demonstratedly effective technology on grounds of cost alone.

- On the other hand, it would not be ethical to approve its extensive use until the economic demands of substantially more cost-effective technologies have been addressed.

- If used only as a bridge to transplantation, to rescue cases in cardiogenic shock who would otherwise have a rapidly fatal outcome, 10 LVADs might be required in the first year. It would be reasonable to initially limit LVAD use to this number.

- Until there is a substantial increase in the effectiveness of this procedure and a reduction in its cost, its application with the intent of providing a permanent substitute for transplantation would lead to inappropriate use of resources.

- It will be difficult to limit the use of this technology. There will be social, political and medical pressures to expand its use to all individuals whom it might benefit. It is

essential that the number of implants authorized be clearly defined in advance.

Significant Practical Issues

Initiation of this technology should not be undertaken without prior decisions being taken on the following issues:

Research. A major reason for proceeding to use LVAD technology would be to contribute to knowledge. The first objective should be a comparison of the outcomes and costs of the technology with conservative management. The relevant clinical and cost data of every case implanted in Quebec should therefore be recorded in a registry with all the rigor of a research study, and a matching control series should be established. Delivery of such research data should be a condition of approval.

Centralization. To maximize the acquisition of skills, LVAD technology should initially be concentrated in a single centre which already carries out heart transplantation and which offers access to all medical specialty services.

Access. To facilitate access, the centre undertaking LVAD technology should establish a functional communications network with other cardiac surgical centres. Some of these should be equipped with devices such as Abiomed® or Thoratec® to facilitate rescue and transport of cases. To receive transfers the implant centre would need to maintain a heart failure unit with appropriate beds and support staff.

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Budget. Existing budgets will not be able to absorb the cost of this new technology. If it is to be undertaken, appropriate funding must be provided outside existing hospital budgets.

Evaluation. The program should undergo thorough evaluation at regular intervals (initially at least every 3 years). At this time, possible extension of the program, or other modifications, must be decided upon. Poor clinical results or failure to produce the research data should be considered cause for transfer of the program elsewhere.

Importance of a Public Debate

Access to an effective technology has not, until at least recently, previously been limited on grounds of its cost. Until the opportunity costs of such decisions (i.e. what we must do without in order to pay for a technology like LVADs) are understood and widely accepted, wise decisions will be difficult to make and apply. In order for the public to comprehend and accept these decisions, there must be widespread and open debate of the fundamental issues raised by allocation of collective resources.