The development of the total artificial heart (TAH) as a support before cardiac transplantation and as a possible permanent prosthesis has generated intense debate. The social commitment to TAH research entails immense health care costs because of the cost of the implant itself and also because of the large number of patients whose interests impel the research. The deployment of the pre-transplant TAH during the current shortage of donor hearts means that the TAH creates its own incentive as a way to compete in an expanded pool of donor heart candidates. Policies to address the orderly deployment and costs of the pre-transplant TAH are needed. Research design and current pre-transplant clinical applications require careful consideration of planning for the termination of TAH support for severely injured but not brain dead patients.

Recent progress with the total artificial heart (TAH) has captured public interest, subjected preliminary human trials to unprecedented scrutiny, and fueled an intense debate among ethicists,\(^4\)\(^-\)\(^10\) policy analysts,\(^4\)\(^,\)\(^5\) federal agencies,\(^6\)\(^-\)\(^7\) and medical experts.\(^6\)\(^-\)\(^10\) Four questions seem fundamental to public policy and the current clinical use of the device: 1) What is the TAH's place on the research agenda? 2) What are the proper clinical and research uses of prototype devices? 3) What are the ethical constraints on the use of human subjects in TAH development? 4) What are the special aspects of informed consent to the implantation and termination of the TAH?

**TAH on the Research Agenda**

**Clinical Benefits**

The ability to replace a failed heart would be life-prolonging for patients who are awaiting transplants as well for those who are not transplant candidates.

**Deployment Costs**

It is argued that modest support for TAH develop-
ment should stop because the eventual costs of TAH deployment are unbearable.6,10,16 This view assumes that the TAH would be less desirable than other costly, but established treatments currently supported by private or public funding.16,17 Adherents of this position conclude that TAH development should be aborted to prevent a successful TAH from entering the democratic arena which would be unable to resist the appeal of a dramatic new technology.

The TAH proponents hold that the modest outlay of $10 to $12 million dollars per year for pre-deployment research on all types of circulatory assistance is the only way to learn about the absolute and relative costs and benefits of a TAH.6,12 The argument that the TAH would draw funds from more pressing health or social needs improperly assumes that funds for TAH deployment would otherwise go to more beneficial uses.3,11,14 TAH proponents also note that the $2.5-3 billion annual TAH deployment costs derive in large part from the many persons who might benefit from the device rather than from unprecedented per-case costs estimated at $30,000 per year.6

Our society encourages scientific innovation for problems like premature death from presenescent heart failure.11,18 In this milieu, the severe and persistent shortage of donor hearts9,43 will fuel ongoing research interest in the TAH.8 Arguments for continued trials of permanent TAH implantation would be more persuasive if short-term TAH morbidity were more completely resolved and if the power mechanism offered independent life. Nevertheless, as Casscells17 has noted, “... cost effectiveness has been a theoretical and unpersuasive argument as compared with a dying child whose parents cannot pay for an operation.” Now that the TAH has demonstrated its ability to prolong life, it is even less likely that social policy will prevent its development and partial deployment.

Because the current TAH is a costly way to prolong life, society might choose to give TAH bridge deployment a low priority for public funds but it is unlikely that privately funded research will stop.8,10 Given the continued allure of this device, active public debate as to how to guide developmental research and the introduction of this technology will continue. Ultimately, TAH research will stop only if the device proves to be ineffective or a predictable cause of complications that are unacceptable to research subjects.

CLINICAL APPLICATION OF THE TAH

Each year, 17,000 to 35,000 persons die of presenescent heart failure, 5,000 to 11,000 become eligible for kidney transplantation, and 5,000 to 10,000 become eligible for liver or pancreas transplants.18 Not all of these individuals will receive new organs—donor organs are scarce, the cost of transplantation is high, and it is incompletely reimbursed.

TAH and Heart Transplantation

Since the first government TAH study in 1967, heart transplants have become a successful treatment for presenescent heart failure.5,17 Three-fourths of transplant patients survive two years;20 more than half live five years.17,22 Many survivors return to premorbid levels of function23 with a quality of life that is comparable to those receiving kidney transplants and better than that of those on dialysis.24

The prospects for TAH recipients are not as optimistic. Even if strokes and infections can be prevented, external power mechanisms severely restrict patients' independence. Implantable power devices are years away.5,25 The implications of the success of heart transplantation for TAH development (either in decreasing the demand for a permanent TAH or in spurring interest in the TAH for pretransplant support of patients) are not addressed in the most recent government TAH study.5

There is a natural tension between research to develop a permanent TAH and easing acceptance criteria for heart transplant recipients.26 The desire for more “survivable” TAH subjects inclines TAH research towards patients who would be better medical candidates for transplants. Permanent TAH research subjects who subsequently become eligible for transplant are particularly troubling; at least one of the early TAH subjects would today have been eligible for a heart transplant simply because age limits have been liberalized.27 Subjects of permanent TAH implantation trials should be evaluated periodically to determine if their ineligibility for transplantation has changed and, if so, what the implications of this are for their continued participation in TAH research.

The TAH as Bridge

Many scientific observers propose that the TAH be employed only as a temporary bridge until a donated heart can be implanted.8,9,10,29,30 One quarter of heart transplant candidates die while waiting for a donor heart.20,27 The shortage of donor hearts and the increasing success and availability of heart transplantation have led to an eight-fold increase in the waiting time of critically ill patients for a donor heart.31 Many believe that clinical experience with the TAH as a bridge will lessen the need for further trials of permanent TAH implantations.

Critics point out that deployment of the TAH as a bridge increases the pool of persons awaiting transplantation without increasing the supply of donor hearts.5,32 The possibility that the limited supply of donor hearts might be preferentially allocated to persons on a bridge17,27 in order to minimize TAH-related morbidity has been especially controversial.27
This proposal would permit patients or a transplant center to elect the TAH in order to compete more effectively for scarce donor hearts. The incentive to choose a TAH becomes greater as the bridge TAH is more widely used and as bridge-supported patients take an increasing portion of the inelastic supply of donor hearts. In the absence of public subsidies for TAH bridges, this practice would tend to allocate donor hearts to persons wealthy enough to extend their stay in the recipient pool by purchasing a pretransplant bridge. Ultimately, the constraining effect of the donor shortage will lead to longer stays and greater attrition of persons waiting on the TAH bridge, just as has happened for cardiac transplantation without the TAH. Such a development would increase the cost of end-of-life care for persons not receiving a transplant by $100,000 per patient.3

Some observers believe that the bridge application might have salutary effects on heart transplantation. Current practices must hurriedly match a donor heart and a small group of imminently dying patients. A large, varied pool of TAH-supported patients might allow allocation of donor hearts to more medically suitable candidates.33 Some experts believe that as many as 10 percent of currently harvested hearts are wasted because of the unavailability of a suitable candidate.28 The availability of a pool of transplant-ready TAH supported recipients might decrease this waste of a scarce medical resource and increase the number of hearts successfully used for transplantation.28,34

**TAH Bridges and Patient Choices**

The availability of TAH bridges imposes a complex and poignant decision on patients with heart failure. Those electing a TAH bridge incur substantial additional costs without a guarantee that a donor heart will become available. Those wanting a transplant, but declining the costs and burdens of the TAH bridge, might justifiably fear that this decision decreases their chance of receiving a donor heart. This Faustian gamble will have profound emotional and financial consequences for family members as well. Public awareness of such choices might help mobilize additional donor hearts,16,40 but it would take a 15-fold increase in the efficiency of donor heart harvesting to meet the projected need for donated hearts for transplantation.5,33

**Quota for TAH Bridges**

A public policy quota might alleviate the adverse consequences of unrestrained TAH bridge deployment by reserving a fixed percentage, perhaps 90 percent, of donor hearts for non-TAH-supported patients. This would reserve 10 percent of donor hearts for bridge patients, approximating the maximum number of donor hearts that may be wasted for want of a suitable transplant candidate.28 Such a quota rests on the premise that all transplant candidates have equally dire need and that using a TAH to prolong life beyond the failure of a natural heart is a benefit that does not create a priority claim to a donor heart. This quota could be enacted as part of a multi-center protocol to prospectively study the extent to which the bridge improves donor-recipient matching, decreases wastage of donor hearts, increases donor recruitment, or facilitates permanent TAH development.8 It might be enforced by restricting either TAH site licensing or access to public funds for TAH implantation.

**Limitations of TAH Bridge Research**

Some advocates of permanent TAH implantation trials believe that restricting the TAH to bridge use would slow permanent TAH development. TAH bridge patients wait an average of only 18 days (range 1- to 111 days) for transplantation,29 presenting little opportunity for extended study of TAH use. Research on bridge-dependent patients is constrained by the moral obligation to safeguard the future transplant, invasive studies that might introduce infections in patients about to be immunosuppressed might not be possible. Finally, additional trials of permanent implantation will likely yield information that will benefit short-term bridge patients.

**TAH Research with Human Subjects**

Research with human subjects is limited in order to protect individuals from being abused by the researcher’s or society’s pursuit of grander social objectives.36 In 1982, the FDA granted an investigational device exemption for permanent TAH implantation because of the absence of other life-prolonging therapies for patients with endstage cardiomyopathy or who are unable to come off circulatory assistance after heart surgery.4,15 This exemption was justified by these patients’ dire need and by the importance of information about how to treat this class of patients.15 Annas8 believes that the prognosis with a permanent TAH is so predictably poor that the exceptional authorization for TAH research is not warranted.

The physician’s duty of beneficence to TAH-dependent patients constrains TAH research in three ways. First, as the current consent form recognizes, separate consents are required after TAH implantation before additional research burdens are imposed on TAH-dependent persons.37,38 Second, research in transplant-eligible patients should not endanger the success of a future transplant. Third, the vital dependence of human subjects on the implanted TAH means that decisions to turn off a TAH are akin to those involving the discontinuation of other life-prolonging treatment, rather than the decision to end an unsuccessful clinical
Several consent issues are raised by TAH implantation including: 1) whether it is possible to obtain TAH consent from critically ill patients, and 2) whether and by what mechanism the TAH may be discontinued in advance of a patient's death.

Despite their dire clinical circumstances, patients do seem capable of giving meaningful consent to TAH implantation. The fact that potential recipients have refused the TAH after becoming aware of its morbidity demonstrates that dire need does not make consent a foregone conclusion. However, consent from seriously ill persons is never entirely free of coercion by fear of death or transference inflation of the attending physician. Rather than voiding consent, as some suggest, the possibilities of coercion and transference serve as reminders that consent cannot confer absolute protection and thus does not confer unlimited license. The consent document merely symbolizes and summarizes the consent process and should not be analyzed as if it adequately represents the consent process.

For procedures, like TAH implantation, that involve a continuing treatment rather than a discrete intervention, informed consent should be viewed as an ongoing agreement, rather than as a discrete event. This process should allow for the possibility that the research interests and patient interests might diverge during TAH treatment and should anticipate complications which might lead to consent being withdrawn.

Termination Planning for TAH Patients

The decision to terminate a TAH resembles the decision to discontinue other life-sustaining treatments like respirators or dialysis. It should be based on the patient's preferences. Though TAH termination necessarily entails death, this is not, as some suggest, suicide, an analogy that has been rejected in reference to other refusals of life-sustaining therapy by terminally ill persons.

Despite improvements in equipment and medical management, TAH implantation will be a hazardous therapy. Some TAH recipients will die after an extended course of multiple organ failure similar to that of critically ill intensive care unit patients. Bridge recipients may well experience complications that will render transplantation impossible. These complications and this manner of dying may be anticipated and should be addressed with patients.

Physicians and patients should prepare for two possibilities: that competent patients who are doing well may wish to stop the TAH, and that patients who are no longer competent may have issued advance instructions for care when they can no longer speak on their own behalf. The dialysis experience, where nearly a fourth of the patients die after elective discontinuation of therapy, often independent of new setbacks, suggests the magnitude of the need for TAH termination planning.

Many forces will make planning for these eventualities difficult. The immediacy of death after ending TAH support will demand steadfastness and sensitivity on the part of participants in such decisions. Physicians will need to recognize that the decision to terminate a TAH research trial lies primarily with the patient. Finally, termination decisions will occur in the public arena that is both fascinated by and unsophisticated about these decisions. Intense scrutiny by the media and partially informed legal authorities may mean that the termination of a TAH may adversely affect the possibility of future TAH research or bridge deployment.

It is likely that patients will be incapable of directly participating in the final decision to turn off a TAH. Advance termination agreements, like living wills or durable powers of attorney, could be used as part of the consent process to provide "relief from the continued beating of the artificial heart" just as they are now used in other settings. These directives should be constructed to protect health care providers from adverse legal action as they act to carry out the patient's wishes. Such agreements should be reviewed periodically with the patient after the TAH has been implanted.

With the patient's permission, termination planning should be conducted jointly with the designated proxy decision-maker. Patients should use durable powers of attorney to name family proxies to act in the patient's interests if the patient is unable to participate in decisions. Such joint planning and proxy designations should prove helpful to families in the stressful time when the patient becomes incompetent. The medical chart should record the proxy's participation in this process. In most jurisdictions, this process would provide significant legal protection for the physician and the institution where the TAH is used.

Conclusion

The TAH poses ethical and public policy issues that are as formidable as the scientific and technical difficulties of TAH development. The task at hand is to develop effective therapies for patients dying prematurely of cardiac failure. The relative shortage of donor hearts will lead to continued interest in the TAH both as a permanent device and as a form of pre-transplantation management despite criticisms of this device. For public policy, the most pressing need is for an innovative policy to responsibly deploy the TAH as a bridge to transplant. For clinicians, the principles of consent and for advance planning for possible termi-
nation of the TAH are similar to those developed for other life support technologies.

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