

Informed Consent Issues in the Cardiac Transplantation Evaluation

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As consultation-liaison psychiatrists to a cardiac transplantation team, we have observed various informed consent issues that are particularly associated with evaluation for cardiac transplantation. We discuss complicating factors that relate to each component of informed consent and present the defense mechanism of denial as a barrier to making the decision to accept or refuse transplantation. Changes in the evaluation protocol could preclude existing impediments to provision of information and patient autonomy; however, certain intrapsychic issues must be recognized as ongoing clinical realities to be addressed as the doctrine of informed consent continues to evolve.

Although the need for general consent to medical procedures has been a feature of Western medical tradition for centuries, champions of patients' rights and the consumer model of doctor-patient relationships have lately urged that patients should be active decision makers in all phases of their medical care.^{1,2} Court rulings throughout the past several decades have been defining and refining the standards of information, disclosure, discussion, and consent that must take place between present-day

physicians and patients.³ In contrast to the lofty goals espoused on paper, many clinicians have argued that the ideal doctrine of informed consent cannot be approximated in everyday medical situations.^{4,5} Lidz et al.⁶ have observed and discussed many of the barriers to the informed consent process in medical settings. Current standards require a direct relationship between the level of invasiveness and risk of a procedure and the quality of consent.⁷ As psychiatric consultants to a cardiac transplantation team we are in a unique position to examine the decision-making process related to informed consent in one of the most serious and invasive of all medical procedures.

The major components of informed consent are information, voluntariness, and decision-making capacity.⁸ We have observed complicating factors

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pertaining to all of these components in the cardiac transplantation evaluation. Whereas the existing complications might not render a consent invalid under present legal standards, the discussion of these issues is worthwhile because it highlights the frequent opposition of clinical realities and medicolegal theory. This paper will discuss impediments to the consent process peculiar to or particularly associated with cardiac transplantations. Each of the components of informed consent will be examined as well as the specific defense mechanism of denial, which presents barriers to several of the components.

Background

The authors maintain a psychiatric liaison arrangement with the cardiac transplantation program of The Louisville Institute for Heart and Lung Disease at Jewish Hospital in Louisville, Kentucky. The transplantation evaluation begins after potential heart recipients are referred by their primary physician or cardiologist. An extensive medical workup ensues, with evaluation by specialists in cardiology, cardiovascular surgery, pulmonary medicine, nephrology, and any other appropriate specialty. The psychosocial evaluation proceeds concurrently with the medical evaluation and consists of psychological testing, extensive patient and family interviews conducted by a social worker, and a full psychiatric examination. When the evaluation is complete, the cardiovascular surgeon reviews and discusses the case with the evaluation team and makes the final decision about the appropriateness of car-

diac transplantation for each patient. This decision is discussed extensively with the patient and family and if the patient is to become an official transplantation candidate he or she is placed on the organ procurement network. Verbal consent to the procedure is obtained at this time; the actual consent document is not presented to the patient until a donor heart has been located. We follow patients for the duration of their involvement with the program and encourage the participation in individual and group therapy to facilitate the adjustment to evaluation, the possible rejection as a candidate, the wait for a donor heart, and the resumption of normal life activities after transplantation. In addition to patient contact, we spend considerable time in interaction with the other members of the transplantation team and are able to observe every phase of the transplantation protocol from several vantage points.

Between August 1984 and June 1987, 79 patients were evaluated for cardiac transplantation. Of these patients, 31 received transplants and 48 did not. Of the 48 who did not receive transplants, 17 were deemed inappropriate for the procedure on medical grounds and nine on psychosocial grounds. Nine did not receive transplants because they died during evaluation or while waiting for a donor heart and five because they decided against having the procedure for a variety of reasons.⁹ The family of one comatose patient decided not to proceed with transplantation. Of the remaining patients not receiving transplants, three were referred to other transplantation programs, three are in

the process of evaluation, and one is waiting for a donor heart. With the majority of cases we were able to observe and discuss the patient's decision-making process as the transplantation protocol unfolded. In all cases we were able to discuss the patient's decision about transplantation with team members who were intimately involved with the ongoing informed consent process. The following discussion represents clinical observations gathered during this consultation experience and applies both to patients who decided against having a transplantation and to those who consented to the operation. Virtually no one to whom the procedure was offered made the decision easily and all struggled with a variety of the following issues.

Issues Involving the Provision of Information

At the foundation of informed consent is the relevant information provided by the physician to the patient so that he or she can reach an intelligent decision about the proposed treatment. This information is generally interpreted to include current medical status, the nature of possible treatments along with their risks and benefits, prognoses with and without treatment, and the physician's opinion on the best course of treatment.⁸ Individual patients may also have specific questions about certain aspects of treatment that relate to past experience or personal values that need to be answered before a decision can be reached. The lack of pertinent information regarding cardiac transplantation can be an unintentional

complication in the ideal informed consent process.

The first heart transplantation was performed 20 years ago and the procedure has been experimental during most of its short history. Only since the recent development of cyclosporine-induced immunosuppression has cardiac transplantation moved into the realm of accepted medical treatment for end-stage cardiac disease.¹⁰ Patients often ask questions about long-term survival and quality of life, chronic rejection, side effects of continuing immunosuppression, and other topics that are not currently answerable. Patients must then reach a decision about transplant without knowledge that they may feel is material to that decision. Uncertainty is unavoidable where medical knowledge is limited; however, some patients can tolerate uncertainty and still reach a decision based on the information available, whereas others may have their decision-making process paralyzed by the lack of answers to specific questions. More than one of our patients has agonized for weeks over the decision to become a transplantation candidate because of doubts about the potential effects of the surgery on their families and themselves.

Other barriers to receiving information lie in the organization of the evaluation process. The deleterious effects of multiple information providers has been mentioned in other settings.¹¹ During the evaluation for cardiac transplantation, patients see a particularly large number and variety of medical practitioners, all of whom have different perspectives and different styles of

communication. Even with the transplantation team's concerted effort to present consistent information, patients often hear contradictory or confusing statements. We have observed information being given in highly technical language by one staff person and in very unsophisticated terms by a second person without the patient's realizing that the same subject had been under discussion. Several patients who became frustrated with this situation began notebooks in which they recorded each doctor's name, specialty, and recommendations in a desperate attempt to sort out the barrage of information.

The time lag between the provision of most of the relevant information about transplantation and performance of the operation also presents problems. Patients in our program receive detailed instruction in all aspects of cardiac transplantation by the coordinating nurse at the time of evaluation. They also discuss the procedure and necessary follow-up with the various physicians, dieticians, social workers, etc., at that time. The actual consent document is not presented to the patient until a donor heart is located and surgery is imminent. With the need for donor hearts rapidly outpacing the supply, patients in our program have waited up to six months between evaluation and transplantation. The less sick patients typically wait at home with a beeper and have only infrequent contacts with the transplantation team. When a donor heart is found, speed in performing the surgery is of the utmost importance. Although the emotional rigors of facing a terminal illness and experiencing a con-

tinuously deteriorating medical condition have profound effects on a patient's goals and values,^{12,13} the urgent nature of the transplantation situation precludes anything other than minimal discussion and reflection at the time of surgery.

Issues Involving Volition

The medical criteria for cardiac transplantation include lack of viable alternative treatments and terminal prognosis. The candidates must meet the guidelines of the New York Heart Association Class IV and most have undergone various medical and surgical treatments that have failed to produce a lasting recovery. Cardiac transplantation is presented as literally the last hope to avoid impending death. In this extreme situation, the voluntary nature of informed consent is open to question.

There have been very few studies addressing the volitional component of informed consent.¹⁴ In the broadest sense the requirement that consent be voluntary is meant to prevent the exploitation of prisoners, captives, or other vulnerable individuals. Cardiac transplantation candidates are vulnerable in the sense that their alternatives are limited to a choice between imminent death, i.e., no transplantation, and undergoing a procedure that offers a survival rate of 70 percent at the first year and 63.5 percent after five years.¹⁵ Patients often describe a subjective sense of coercion to consent to transplantation that stems from the natural course of the illness rather than the physician or any other external agent. Psychiatrists participating in transplanta-

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tion evaluations have commented on the frequent statements patients make about the lack of choice due to the prospect of death.¹⁶⁻¹⁹ We, too, have noted this theme running through our evaluations. One 42-year-old male patient summed up his feelings about the alternatives by saying, "You really have no choice. When you're drowning even a leaky lifeboat looks good."

Besides the patient's awareness of approaching death, there are other issues that can interfere with the voluntary nature of the transplantation candidate's consent. One issue is the enthusiasm of the transplantation team. Being involved in a well-publicized procedure on the cutting edge of medicine is very exciting for team members who work long hours together in emotionally laden situations. Each team member's total dedication to the idea of cardiac transplantation is inherent in the team's functioning. Without really considering their own wants and needs, impressionable or passive patients can be swept away in the tide of enthusiasm and unspoken expectation that every patient would choose to have a cardiac transplantation if offered one.

A related, but separate barrier to the voluntary nature of consent is the "assembly line" style of referral and evaluation in which different physicians evaluate patients according to a highly structured protocol. At each stage of the protocol, the physicians tend to assume that the patient has "chosen" to have the operation or he or she would not be there. In reality, the patient's referring physician may have given the patient very little relevant information

about transplantation. One outspoken 52-year-old white man who underwent a lengthy evaluation remarked, "Everyone keeps telling me what they're going to do with me after the transplant, but I haven't even decided if I'm going to have this thing." As with the issue of team enthusiasm, a passive or dependent patient may not have the assertiveness to jump off the assembly line. All of these influences are much more subtle than outright coercion, but they nevertheless interfere with the patient's autonomy.

Issues Involving Decision-making Capacity

Capacity is the most studied facet of informed consent and, in clinical situations, deficits in capacity tend to produce more doubts about the validity of consent than do deficits in information or voluntariness. Many transplantation patients have cognitive problems or other mental status changes secondary to their deteriorating cardiovascular conditions and are unable to process information and reach a rational decision about transplant. As the informed consent issues relating to these patients are not significantly different from those discussed in previous studies with regard to other medical procedures,^{20,21} it will suffice to say that we have observed several instances of third-party consent because of transient organic mental disturbances compromising the patient's decision-making capacity. In these cases the medical team accepted the family's written consent for the procedure.

Issues Involving Denial

Evaluation for possible cardiac transplantation provokes a variety of emotional responses that have the common function of keeping anxiety at a minimum and maximizing hope for recovery. Denial is one of the defense mechanisms that psychiatrists working with cardiac transplantation patients have seen in patients at various stages of the transplantation protocol.^{17,22-25} The prominent emotions of relief and renewed hope at being accepted as a candidate and being placed on the organ procurement network have also been noted.^{17,19,25} Lacking the prospect of any alternative treatment, many patients incorporate the idea of transplantation as a last-ditch rescue fantasy.

We have observed that many of our patients come to the evaluation process with their minds made up to have the transplantation. They focus on the positive aspects of the proposed surgery and often emphasize the miraculous quality of the technology involved. To some this process seems like an almost magical solution to their life-threatening problem. If, because of his or her personality style and previous experiences with illness, the patient copes with the stresses of transplantation evaluation by use of this unconscious rescue fantasy, then strong denial often comes into play regarding the drawbacks of the procedure. When being instructed on the risks and benefits of the proposed operation, these patients often do not hear or do not attend to the long list of possible complications. Patients using denial tend to ignore information about

the ever-present risks of rejection and infection and to minimize the possibility of problems with the donor heart, hyperacute rejection, or any other intra-operative complications.

When assessing patients' understanding of the risks and benefits associated with cardiac transplantation, we frequently hear such statements as, "None of those bad things will happen to me; God wouldn't have offered me the chance to have a new heart if it was my time to die." The use of denial of a possible bad outcome obviously provides a strong coping advantage for these patients. One 58-year-old man who had never experienced any sort of surgery became so anxious when the information about the risks of transplantation and associated diagnostic tests were presented to him that he refused to read any consent forms. He signed consent forms for an arteriogram, the transplantation itself and posttransplantation cardiac biopsies without reading them, often using the excuse that he had not brought his glasses. When questioned about this behavior, he stated, "There's no sense in making myself nervous." When not reminded about the details of upcoming procedures, this patient remained fairly calm and hopeful that "the Lord will see me through." Roth *et al.*²⁶ have described the dilemma of psychiatric patients' denial of illness in assessing competency to give informed consent. They concluded that the patients' "appreciation of the nature of his or her situation is crucial." Regarding decision making about cardiac transplantation, the issue is not

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usually denial of illness but denial of the very real and serious risks associated with the proposed treatment. The unconscious refusal to consider the possible morbidity and mortality of transplantation strikes at both the informational and competency components of the doctrine of informed consent. Information cannot be completed if part of it is ignored, and capacity to understand is compromised if overwhelming anxiety triggers a defense mechanism that blocks out or minimizes part of the total picture.

Of course, some exceptions to the doctrine of informed consent could be invoked in the case described above. The patient who signed the consent forms without reading them effectively communicated to the medical team that he wanted the transplantation but did not wish to be informed about the risks. For all practical purposes, this patient waived his legal right to give informed consent. It might also be argued that the medical team, sensing the great anxiety aroused in this patient when his denial was shaken, might have withheld negative information on the grounds of therapeutic privilege. This exception to informed consent is allowed because of harmful effects that certain information might have on the patient. Both of these exceptions have been discussed in the literature on informed consent and have some validity in case law.^{8,27} On a philosophical basis, however, it seems that either the patient's denial or the physician's decision to suppress some relevant information strikes at the very

heart of ideal informed consent, i.e., shared decision making.

Conclusion

The cardiac transplantation setting provides avoidable and unavoidable complications in the informed consent process. Some of the transplantation protocol conditions that interfere with the provision of information or patient autonomy could be improved with better planning based on sensitivity to these issues. For example, the volitional nature of a patient's decision could be enhanced by staff perception of transplantation refusal as an acceptable and rational alternative for some patients. To improve the quality of the informational component, transplantation centers should organize the educational and information-giving process through one key staff person who integrates various test results, recommendations, and other material to give the patient a daily update and to answer questions.

However, the intrapsychic conditions that accompany a transplantation evaluation are inextricably bound up with the experience and cannot be handled by adjustments in the protocol. In the case of denial that is serving a protective function, an argument can be made for not trying to shake the patient's defense by forcing information on him or her. This route does not seem to be generally effective, anyway, as we have noted that patients who are not ready to consider the risks will not do so no matter how explicitly they are presented. The conclusion that we draw

from these psychological barriers to decision making is that those who make medicolegal policy and those who examine the doctrine of informed consent from a philosophical basis should understand the clinical realities and apply this understanding as the doctrine continues to evolve.

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