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THE PHYSICIAN'S INFLUENCE ON INFORMED CONSENT FOR BONE MARROW TRANSPLANTATION

ABSTRACT. The influence of physician judgment on the disclosure, competency, understanding, voluntariness, and decision aspects of informed consent for bone marrow transplantation are described. Ethical conflicts which arise from the amount and complexity of the information to be disclosed and from the barriers of limited time, patient anxiety and lack of prior relationship between patient and physician are discussed. The role of the referring physician in the decision-making is considered. Special ethical issues which arise with use of healthy related bone marrow donors are discussed, as is the physician's discretion in raising questions of competency. It is concluded that in this setting, regardless of the theoretical goals of the physician, patients appear to utilize informed consent discussions to assess their capacity to trust the physician rather than as a time to weigh the large amount of relevant data. The conscientious physician best serves the patient with recommendation of the best medical alternative rather than with attempts to remain neutral.

Key words: Bone marrow transplantation, Informed consent, Physician role, Organ donor.

INTRODUCTION

Informed consent regulations for patients in most American hospitals require that patients be fully informed by their physician of the nature, risks, and benefits of and alternatives to any medical procedure which is proposed. When the procedure being considered is a complicated, high-risk treatment with experimental aspects like bone marrow transplantation, the requirement to describe the procedure (or series of procedures) and to list and interpret an array of serious potential side-effects places a considerable burden on the conscientious physician. It assumes that the physician both has the time and patience to fully explain histocompatibility testing, high-dose chemotherapy, total body irradiation, marrow harvest, possible treatment of the marrow, marrow infusion, graft rejection, Graft-Versus-Host-Disease, infectious risks, and long-term survival prospects for the patient contemplating transplant. Minor side-effects, psychological aspects, and potential risks to the donor also need to be explained. The often sensitive and painful subject of alternative treatments (or in many cases, the absence of life-saving alternative treatments) must be discussed. Explanations are necessary for the patient, for the donor, and in the case of minor patients, for the parents. Each family member may have a very different level of understanding and investment in the

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procedure. It is assumed that the physician is capable of assessing the child's or adult's level of understanding and modulating his/her information delivery to the appropriate level of detail and sophistication. It is assumed that he/she is perceived as sufficiently open so that questions can be raised by the potential patient or donor. And, finally, it is assumed or at least hoped that this information can be conveyed without bias.

Are these expectations reasonable? Are they fair to the patient or to the physician? Do they lead to the results intended by informed consent regulations? And what are the ethical dilemmas presented when these expectations cannot be fully met?

With about 100 bone marrow transplant (BMT) units currently operating in the United States, a growing number of physicians are facing the questions of how best to approach potential transplant patients. The issues raised for bone marrow transplant also have implications for patient-physician interaction in other areas of transplantation and in high technology medicine generally. We would like to analyze the burden on the bone marrow transplant physician in light of what is known about informed consent and in light of our own clinical experience of ethical dilemmas found with our patients. We shall utilize the conceptual model of informed consent devised by Meisel and Roth in their critical review of the informed consent literature (Meisel and Roth, 1983, pp. 271—272).

DISCLOSURE OF INFORMATION

The initial major judgment the bone marrow transplant physician must make is how detailed the information he gives his patients should be and what emphasis or interpretation he should give to each risk factor and to survival statistics. The physician's task is to be honest and direct without overwhelming the patient. But bone marrow transplant is a complicated, frightening process with a mystical aura in the lay press. The range of what patients arrive knowing about transplant is vast. Some have been told by ill-informed referring physicians that bone marrow transplant has cure rates of up to 100% with little or no mention of risk factors. The pressure on the bone marrow transplant physician is increased by the nursing staff who want to be reassured that patients know what they are opting for in the choice of bone marrow transplant. And there is, of course, the physician's own commitment to his field and his personal belief in the efficacy of transplantation. This is all background for his attempt to comply with legal requirements and to fulfill his own ethical standards of providing honest, straightforward information to patients without being

coercive. While physicians vary in their views of how much influence their personal opinions should have in patient decision-making, they will, for the most part, agree that the patient has the ultimate choice without becoming totally responsible for his or her own care. And yet, all but the most paternalistic will question some aspect of their method of delivery of this information to at least some patients.

Problems in disclosure for bone marrow transplant begin with an overdose of information. Bone marrow transplantation is really a series of procedures occuring over a period of months to years with one comprehensive consent form. As pointed out earlier, such consent must cover a host of complex subjects, including a significant number of different possible results of the procedure. Knowledge of bone marrow transplant is outside of the experience of not only well-informed lay people but also of the majority of physicians, even specialist physicians. While legally the option exists to stop treatment at any time, practically, there is a *point of no return* (i.e. lethal body irradiation) after which point the decision not to continue treatment is equivalent to choosing to die within a few days. The seriousness and consequences of signing the consent form and agreeing to a transplant cannot be greater; this is in all cases a life and death decision which rapidly becomes irrevocable. The importance of the communication between patient and physician assumes paramount importance.

A study by Epstein and Lasagna (1969, p. 684) shows that the longer the consent form, the less people understand of it. Because of the extreme nature and complexity of bone marrow transplant, our consent forms average four pages. Other studies show that patients are helped by having adequate time to discuss the consent form with the physician, preferrably over several visits, and by taking a copy of the consent form home to discuss with others (Silberstein, 1974, pp. 155—6). This is not only time-consuming for the physician but often difficult to arrange since many patients come from great distance to a transplant center and often arrive committed to but relatively uninformed about the procedure. Also the natural history of some of the patients' diseases require a relatively short time gap over which consideration of transplant is possible.

Because of the specialized nature of the bone marrow transplant procedure, patients have most often been referred first to a regional hematology-oncology facility and then further referred to a center specializing in bone marrow transplant. (In some cases the secondary center also performs bone marrow transplants.) Thus, not only is the information necessary to make a decision complex and explained by a physician who has not yet established a bond of trust with the patient, but the information may be ill-understood by the referring physician(s) who

may, therefore, not be able to play a constructive role in the process. It is also true that the attitudes of the referring physician and the discussion and decision-making between the referring and transplant physicians may result in the elimination of many potential transplant patients on both medical and non-medical grounds.

The next issue of disclosure is that of selection and emphasis of information which arouses the fear of saying too much or saying too little. A balanced explanation is necessary but potential risks take more time to discuss than potential benefits. To make light of the seriousness of the side effects would be to mislead the patients even in the face of the absence of alternatives. But to be so graphic in describing the possible risks that the patient is frightened away from their last hope for long-term survival would also be unfair and unethical. The bone marrow transplant physician is offering both the possibility of truly saving a life but also the uncertainty of outcome which might include accelerated death or increased morbidity. This is so since death from the patient's underlying disease, while statistically certain in many cases, may take months or even 1—2 years to occur, while death following bone marrow transplant could occur within weeks.

The many patients who come to the bone marrow transplant physician in hopes of finding a *magic bullet* treatment which grarantees cure are disappointed during initial discussion. While patients understand when the physician speaks of the risk of death, they have great difficulty fully grasping the enormous impact of the morbidity which may result from bone marrow transplant. This set of circumstances obviously leaves much room for physician self-doubt. We have wondered, for example, how one conveys accurately the risk of a serious chronic and debilitating disease like Graft-Versus-Host-Disease (GVHD). This is a complication of bone marrow transplant which may leave a patient with an external appearance similar to that of a burn patient with, additionally, severe jaundice and chronic diarrhea. Is it sufficient to state the probability of this disease occurring post-bone marrow transplant, a disease which the patient may well never have heard of and almost certainly never seen? Is a brief listing of the symptoms enough? Should one reveal the severity of the psychological distress and depression which GVHD, in its most severe form, has led patients to? We have wondered if photographs of patients with severe GVHD would help potential patients (especially those at high risk of GVHD) to truly understand the risk they are exposing themselves to. Research in this area of informed consent seems to show that patients do not decline procedures after disclosure of negative side effects even though disclosure may increase anxiety and apprehension (Leydecker *et*

al., 1980, p. 244; Alfidi, 1971, pp. 1325–28). The case can be made that this anxiety is realistic and may help the patient set reasonable expectations for the procedure ahead. But the question is: when does the anxiety become detrimental when other alternatives preclude long-term survival? The difficulty of interpreting the Hippocratic mandate to *Do No Harm* is very great in this circumstance. It is issues such as this which leave the most ethical physician questioning the correctness of his/her approach.

We recognize that we operate primarily out of a therapeutic rationale, believing that our primary, although not exclusive, concern is with the preservation of human life and the alleviation of suffering, tempered by respect for patients' rights to information about the procedure in question and about alternative treatments. As such our approach is rather like that described by Sir John Donaldson, Master of the Rolls of the Civil Division of the English Court of Appeals (Schwartz and Grubb, 1985, p.20). He states

> A doctor's duty of care, as the profession would readily concede, involves his evaluating risks and weighing advantages and disadantages before recommending a particular type of treatment. But, having decided what to recommend, there must be a natural, and, up to a point, praiseworthy desire that the advice shall be accepted and a strong temptation not to say anything which might lead to its rejection and so frustrate the doctor's prime object, which is to maintain and improve the patient's health.

This view is different from a rationale which holds the patient's right to make an autonomous decision as the primary concern. Application of these different viewpoints would result in different selection of information to be presented to the patient. Informed consent regulations appear to be based more directly on the autonomous rationale. Our belief, however, is that, for bone marrow transplantation at least, the vast amount of relevant technical information, the many uncertainties, and the high level of patient anxiety, make it impossible for the potential bone marrow transplant patient to digest all of the relevant data to make a truly autonomous decision without editing and selective emphasis from the physician. What the specialist physician has taken years to learn must be digested and acted upon by the patient in a period of days to weeks. We therefore favor the therapeutic rationale as a more humane approach, more in keeping with the Hippocratic tradition.

Word choice is a related area of difficulty which perhaps represents a microcosm of the issue of selection and emphasis. There are many anxiety-provoking words mentioned in a thorough discussion about bone marrow transplant (*death, sterility, recurrence of leukemia*) and the directness of the physician's word choices may have important ramifications. A study by McNeil (1982, p. 1259) reported that experimental

subjects asked to assume they had lung cancer and to choose between two alternative therapies, radiation and surgery, chose radiation less often when it was specifically identified (*radiation*) than when the same information about risk and outcome was given but it was referred to as *Treatment B.* While it is not clear that actual patients would be so affected by wording, in being direct with our patients we are always at risk of using words which provoke more dread than we can anticipate. Word choice is also a way a physician can purposely alter the tone of the informed consent discussion. If the physician feels strongly that a transplant is not in the patient's best interest, his descriptions of symptoms, etc. will consciously or unconsciously reflect his own viewpoint. Similarly, a physician committed to the procedure may choose to diminish the harshness of the complications.

Another problem for the physician in disclosure about bone marrow transplant is that while there are many known risks, the procedure is also complex and still experimental enough for us to know that there are complications which cannot be anticipated. Thus, in addition to presenting the frightening side effects listed in the consent form, the physician must prepare the patient for the additional uncertainty of unanticipated side effects. Even for the known risks, the physician is himself uncertain about which will affect any given patient. This complex discussion often occurs in the context of a doctor-patient relationship whose only trust is that transferred to the bone marrow transplant physician by the referring physician.

The individual physician is in most cases alone in deciding how to make these decisions and his personal view of how much information is valuable, appropriate, and ethical will in many cases be the deciding factor in what the patient is told. Because of the quantitative *overdose of information* that must be outlined to the patient, the relatively short time available for decision-making, the qualitative difficulty of the concepts, and the unfamiliarity of the issues to well-educated lay people and even to other physicians, we believe that it is the accompanying verbal explanations of the physicians obtaining consent which govern what information is in fact perceived by the patient as relevant for his/her decision-making. In fact preplanned explanations are frequently altered by the tone of the ongoing discussion. Although a multi-page consent form may be reviewed and approved by both a group of involved physicians and an institutional review board, it is the unregulated *how* of the physician-patient discussion, not the *what* of the consent form, that is important.

COMPETENCY

In bone marrow transplant there are two times when the question of patient competency is relevant. One is at the signing of the initial consent form. Here the issues are the classic ones of incompetency by virtue of age, cognitive ability, and mental status. The later concern is at a decision point some time into the several months of the transplant process when the patient may be judged by virtue of his physical or psychological condition to be incompetent. Many of these later judgments are similar to those which need to be made in other intensive care unit or high-technology medical situations. While legal precedents are clear in matters of age and what constitutes legal competency, the physician's personal judgment will determine in many cases whether issues of competency are brought to the fore or not. Because little has been written about these issues in the context of bone marrow transplant, two case examples from our experience may be relevant.

The first concerns the physician's decision to transplant a 27 year old retarded man. The issue here was not competency to consent which all agreed was the responsibility of the man's parents by virtue of his intellectual level in the mildly retarded range. The issue was the physician's judgment of the patient's competency to understand and to cooperate with the many rules and daily self-care responsibilities which are part of the transplant experience. The transplant physician believed that although this patient would require extra nursing care, that he would participate sufficiently and that he deserved an attempt at this life-saving treatment. This judgment was questioned by an astonishing number of the bone marrow transplant physician's colleagues who felt that this was a poor utilization of scarce resources. The transplant physician's personal view that the degree of retardation did not in itself constitute grounds for refusal to transplant a patient had a major role in the decision. A physician with opposing views might well have made the judgment that this patient would not have been sufficiently able to follow the necessary instructions and limitations within the transplant room and the patient might therefore have been denied a transplant.

Similarly, in the second case, a desperately ill French-speaking patient was judged by the physician as competent to consider, after his graft rejected, the possibility of a second transplant. With a physician who spoke French translating, the bone marrow transplant physician slowly and painfully informed the patient of his very limited options. The patient asked to have 24 hours to consider his decision and this was agreed to. The patient died the next morning. Another physician might have

concluded that the level of pain and distress this man was in constricted his ability to make a well-reasoned decision and the responsibility for decision-making would then have been transferred to his family.

In both of these cases, the decision of competency could have been made either *for* or *against* by the attending physician and yet would have remained within the legal and ethical bounds recognized by the institution. Furthermore, the time course available for decision-making, in the second case at least, would not permit realistic participation by others. Again, the decision of the individual physician, made in the context of his own ethical standards, appears to be the pivotal force under these pragmatic circumstances, even if the physician would prefer a completely non-paternalistic role.

UNDERSTANDING

While the regulations do not obligate the physician to assess the patient's understanding of what he/she has been told, such an assessment is implicit in the notion of informed consent. For the transplant physician the assessment of the patient's understanding is not easy. Because of the highly technical terms which must be explained, it is easy for the patient to be overwhelmed. The ability to simply repeat the explanation does not necessarily imply understanding. Patients with higher levels of education, particularly medical education, may require less translation, but it is also easy to overestimate how much information such patients have. It is, in fact, often the patients with a medical background who present themselves as transplant candidates against the advice of their own physician when they are clearly inappropriate candidates on medical grounds.

The physician's status and role as gatekeeper may inhibit some patients from revealing areas of confusion in their understanding. Furthermore, patients may have high levels of anxiety about the content of the informed consent discussions. Pain, illness, and a wish to deny the gravity of the situation may further compromise the patient's ability to hear what the doctor has said. A common problem is the over-zealous patient, the one who shrugs the side effects away saying, "I know they won't happen to me. I'll be fine." It is likely that some version of this message is what all patients must come to in order to submit to such a risky procedure. But it is the physician who must judge if this is adaptive denial occurring after the patient has absorbed enough information to make a sound judgment or if this is denial precluding a sound judgment. The physician's ability to make such assessments may be influenced by the degree of confluence

between the decision and his/her own wishes, but may also be subject to the amount of time the physician has available to get to know the patient, by the physician's willingness to utilize other staff who can help assess the patient's level of understanding, and by his/her own sensitivity.

A dilemma is created when the physician finds that he/she agrees with the patient's decision for a transplant as the patient's best alternative, but believes that the patient made this decision either for faulty reasons or because he has failed to fully consider the pros and cons out of a wish to deny the precariousness of the situation. It is not the physician's mandate to assess the patient's motivation per se, but some assessment of motivation is necessary for the physician to decide if he has sufficently informed the patient. In the circumstance described the physician of our team would be likely to make a second attempt at presentation of the material, but after that attempt would be most likely to initiate the transplant process, even if the patient's level of denial remained high. Recognition of limits to the physician's time and ability to assess the patient's psychological make-up and belief in the value of relying on the physician's best-alternative judgement in the absence of patient opposition would lead to initiation of treatment. The alternative of withholding treatment until a better considered judgement could be made has more potential risk to the patient than the risks of proceeding. Since all patients report feeling in some way unprepared for the transplant experience, this might be considered simply a more extreme case. This approach may well again represent our choice of a therapeutic as opposed to an autonomous rationale as a guiding principle.

The physician's self-assessment of his/her ability to talk to children and to explain the transplant procedure to minor patients or to minor donors is beyond legal requirement but will have an important effect on the doctor-patient relationships. Some physicians define this communication as one they consider clearly within their realm of responsibility and expertise while others reject this role in favor of having the child's parents explain the procedures to them with the physician available for clarification.

The role of physician as gatekeeper, especially in this tertiary referral setting, once again, puts high demands on the establishment of mutual trust between physician and patient during the informed consent procedure. Only with such trust can the physician and patient speak honestly regarding the level of understanding. Because of the issues raised earlier about the necessary unknowns in highly complex procedures like bone marrow transplant, it is clear that some minimum level of trust is necessary both for the patient to state his/her lack of understanding of some aspect

of the procedure and for the physician to state his/her ignorance about all the conceivable eventualities. Although such an admission on the part of both the patient and physician might appear to destroy the potential benefits of *benign paternalism* in a desperate setting, we believe that this is not the case. Rather, we believe that it is an essential part of the establishment of the long-term relationship needed for such a demanding procedure.

The view that such an admission of uncertainty on the part of the physician may lead to enhanced rather than diminished trust differs considerably from the more paternalistic viewpoint which says that the patient must view the physician as omniscient in order to believe that the medical care is "the best possible." We hold the view that in the 1950s and 60s during a period of scientific hegemony, the technically competent physician was regarded with awe. This often meant that trust in a physician precluded the questioning of his/her judgement and precluded, on the physician's part, discussion of areas of uncertainty or ignorance. In recent years, as some disillusionment with scientific medicine has set in, and a more balanced public view of the role and abilities of the physician has emerged, admission of uncertainty to patients has become more acceptable. Indeed, we believe that especially in the bone transplant situation trust is rather increased by frank discussion. We believe this is so for two reasons. First, so many staff people are involved in caring for any one marrow patient (an average of 60) that any deviation from truthful and full disclosure would be likely to reach the patient and thereby undermine his trust in the physician. Secondly, marrow transplant demands that the patient is actively involved in his own care. The passivity of the surgical patient, for example, is not possible in this setting where the patient's cooperation is essential to the success of the transplant. We believe that the compliance of the patient is most likely when his understanding of the rationale underlying procedures is greatest. Because, however, of the high level of uncertainty inherent in marrow transplant, it is necessary to share with patients both what is and what is not known. We feel that trust develops from the view of the physician as a fallible but honest, competent, and forthcoming human being. If one is told when the physician is not certain of the cause of a problem or the side effects to be encountered, one can at least understand the need for sometimes rapid changes in medication or other treatment. And when the physician who has been open about areas of uncertainty presents other information as clearly known facts, he is, we think, more likely to be believed and trusted by even skeptical patients.

VOLUNTARINESS

With many patients and donors stating, "There really was no choice," the question of voluntariness in bone marrow transplantation is a difficult one. Because of the many risks, bone marrow transplant is not proposed unless other treatment alternatives are unlikely to provide long-term survival. However, since most bone marrow transplant units are located in tertiary care centers, a good deal of self-selection has already occurred at the level of the referring physician's office. Patients who come for evaluation at transplant centers have passed initial telephone assessment of their medical condition and they have *voted with their feet.* As a result in the past thirteen years we have had only five patients who came to our unit and then decided against transplantation. Nevertheless, from an ethical standpoint, the alternative of other or no treatment must be considered with each patient. The question of coercion may arise in situations where a minor, particularly an adolescent, is opposed to a transplant his parents agree to (or vice versa) and in situations where the patient or, particuarly, the donor is being pressured by family members. The question of how much weight to give adolescents' views on transplant may be answered in part by the study done by Weithorn and Campbell (1982) which showed that fourteen year olds did not differ from adults in their competency to make informed consent decisions. Since one needs the cooperation of a transplant patient, an unwilling adolescent would be likely to be a very poor transplant candidate, although legally the decision remains with the parent.

There have been newspaper reports of family members who refused to be a bone marrow donor, but the publicity about these cases reflects their rarity and unreported mitigating circumstances may exist. In Massachusetts the courts imposed regulations requiring minor donors to have legal representation and to be evaluated by a psychologist to prevent coercion due to intra-familial pressure. In addition, the senior transplant physician in our unit has offered each prospective transplant donor over the age of 18 the option to provide him/her with a false medical counterindication to donation should the donor wish not to donate. This is discussed after consideration of the facts about donation and the patient's need for transplant. This offer is clearly a personal ethical decision on the part of the physician. While it has never been acted on, it is designed to try to avoid serious family problems for the donor who does not stand to benefit, himself, from the procedure and ethically should have the option not to participate. It is based on the complicated ethics of this complicated process. While it may be thought that this approach could reduce trust in

the physician as truth-teller, it is in the service of the wish to "Do No Harm" and in the hope of freeing the unwilling donor from possible life-long family resentment.

The desire to protect the donor again emphasizes our perception of the inability to conduct such informed consent in a truly laissez-faire way without violating the basic ethical necessities of the physician's role as comforter, gatekeeper, and patient advocate. While the patient is certainly not a volunteer, even the healthy donor is not in a position of true voluntariness, given the pressure of family expectations. It is the physician (and in some cases the court) who tries to minimize the coercive aspects of the situation.

Some ethicists might hold that pressure exerted on the unwilling donor by family members is not coercion. They might hold that such pressure is legitimate based on the unwilling donor's seeming rejection of the mutual obligations which bind family members. As such they might perceive our offer of a *donor lie* to be an unnecessary interference in the life of the family. The question of what constitutes and delimits the potential obligation of a family member to be an organ donor is a fascinating question largely beyond the scope of this paper. Suffice it to say that while we have not yet encountered the refusing, related donor, we have seen examples of the other side of the continuum, including donation by a natural brother of a patient who had been adopted and who had had no prior knowledge of his natural siblings. We also receive calls from unrelated volunteers offering to donate bone marrow to meet what they believe to be a societal obligation. We are, in offering to protect unwilling family donors, not making a value judgement on the legitimacy of their choice, but simply trying to limit the potential psychological damage to a donor of refusing an organ donation of no direct medical benefit to himself.

Some physicians new to participation in the bone marrow transplant consent process might prefer to try to avoid "paternalism" and attempt total neutrality, to *wash their hands* of any potentially bad outcome. Some referring physicians may also try to take a completely laissez-faire approach, recommending only consultation with the bone marrow transplant expert, although it is clear that this referral usually carries the weight of recommendation. While the laissez-faire approach may serve to relieve the physician of the uncomfortable role of decision-maker in cases where the decision may result in death or severe morbidity of the patient, it is not clear that it meets the criteria to *Do No Harm.*

DECISION

While there are many assumptions about informed consent, perhaps the most basic is that the physician will not be influenced by capricious, selfish, non-medical aspects of the case in his/her presentation of the risks and benefits of the procedure. It is hoped that the physician will not attempt to deter patients because their condition would be likely to lower his *track record* or to avoid a battle with the billing office because of the patient's financial status. On the other hand, the fact that the patient has some unusual symptoms or traits of scientific interest should not lead to pressuring reluctant patients. And, while bed availability is often a reality factor to be considered, bed availability should not pressure the physician to encourage poor-risk patients to decide in favor of transplantation. The *vibes* between patient and doctor, the degree to which the physician has been *grabbed* by the patient or has decided that the patient would be unpleasant should not influence him/her. However, if the unpleasantness extends to an evaluation that the patient would be likely to be seriously non-compliant or unable to stay in the transplant room, thus increasing the risk to the patient himself, this consideration would play a major role in decision-making.

Further, political pressures may play a role despite wishes that such pressures did not exist. It is at this point that the physician's own views about the value or existence of informed consent surface. It is here where his respect for the patient's right to opt for or against a transplant has its final influence. Research (Novack *et al.*, 1979, p. 897; Oken, 1961, pp. 1120—21; Taub, 1982, pp. 61—2; Faden *et al.*, 1981, p. 271) shows that physicians' personal views have more impact than legal requirements on what doctors tell patients and that doctors who completed their training before 1960 tend to be considerably more paternalistic. The physician must decide in advance what to say when asked what he would do if he were the patient or the parent in this case. Does he offer his personal view or does he turn the decision back to the patient or parent as a judgement he cannot make for them?

An uneducated, illiterate father of a two year old Appalachian girl listened to the whole informed consent discussion and then, apologizing for his illiteracy, said, "Doc, what would you do if she were your daughter?" Our belief is that most patients make decisions in the manner of this father and not in the independent, objective way hypothesized by the Institutional Review Boards which make informed consent regulations. This conclusion is shared by Meisel and Roth (1983) who, after reviewing the literature on informed consent, believe that generally medical decision-making is not the careful weighing of risk and benefit. They concur with

Lindhlom and Cohen (1979) who believe that, "for social problem-solving ... people will always depend heavily on ordinary knowledge". It becomes clear that the physician, the acknowledged expert in this highly specialized field, cannot help but have a major role in influencing the view patients have of bone marrow transplantation and of its efficacy as a treatment for them. If a physician avoids capricious slanting of the information, then what is offered or recommended is actually the best alternative for the patient, not a pure gamble as some patients come to view the choice.

If, then, there is too much specialized information to be transmitted with accuracy and without bias in the available time and there are too many individual judgements concerning competency and voluntariness to allow for complete physician neutrality, what is the major purpose and focus of the informed consent process in bone marrow transplantation? Is it simply a ritualistic formula satisfying a legal-ethical requirement and assuaging the physician's conscience? We believe that this is not the case, but that the informed consent procedure best accomplishes its' goals when it functions as a trust-building exercise between two strangers. While it is not possible within the short time available to master the many facts and uncertainties of bone marrow transplant, it is possible for both physician and patient to judge if they can establish sufficient mutual trust to allow this major procedure to be initiated. This mutual trust is not for purposes of assuring the patient's acceptance of all of the physician's recommendations. Rather, mutual trust is necessary as the basis for the continuing dialogue, the on-going processes of informing and consenting which physician and patient are involved in through the many months of the transplant procedure. Since we believe that *not to decide is to decide* in bone marrow transplant, complete laissez-faire consent is intrinsically impossible and the physician must realistically recognize his/her role in making the decision with, not for, the patient. We can only hope that physicians will remain open to self-assessment of their role as influencers of the decision-making process and that examination of the ethical issues will provide more help for physicians in clarifying that role.

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