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I Had Already Made Up My Mind": Patients and Caregivers' Perspectives on Making the Decision to Participate in Research at a U.S. Cancer Referral Center

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Abstract

Background—Hematopoietic cell transplants (HCT) are associated with high morbidity and mortality which complicates the decision-making process for people considering HCT clinical trials. There is a lack of research examining longitudinally how patients make clinical trial participation decisions in U.S. cancer referral centers.

Objective—A qualitative study was conducted to examine how patients and their family caregivers decide to participate in HCT research at a U.S. cancer referral center.

Methods—Semi-structured interviews were conducted with 25 patients enrolled in early-stage Phase II HCT research studies and with 20 family caregivers. Interviews were conducted before HCT and approximately days 80 and 365 post HCT.

Results—Most patients (92%) and their caregivers (75%) decided to participate in research well before consent conferences at the cancer referral center. Patients' reasons for deciding to participate included having "no other option," seeking a cure, and following their home oncologists' recommendations.

Conclusion—Currently, U.S. researchers are primarily guided by Federal regulations that view the decision-making process as a cognitive one. Findings confirmed cognition was a part of consent, however most patients made the decision to participate in high-risk clinical trials long before they had been apprised of the specific information about the study and before the consent conference.

Implications for Practice—The high risk of death from the disease and/or the HCT underscored the emotional component of decision making and affirmed that researchers need to acknowledge this emotional component in order to meet the ethical imperative of providing "informed consent".

Introduction

The decision to seek oncology care at research center often mandates that patients leave their home communities, interact with unfamiliar physicians and care providers, and follow a course of care that has a substantial research component in which the outcomes are difficult to predict. An important element of cancer research is helping patients arrive at

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satisfactory decisions about their medical options, including participating in a clinical trial. The juxtaposition of research and cancer care requires that due diligence be given to ensure patients have a clear understanding of the decisions they face. Making decisions in these circumstances is rarely straightforward and numerous complex factors influence clinical decision-making processes.

In clinical research, informed consent is the process for addressing issues of decision making. The premise underlying informed consent is that an individual, once given adequate information, can then make a voluntary decision about engaging in whatever option is deemed best for the specific situation. The overwhelming majority of articles on cancer and decision making focus on communication patterns between patient and provider,[1–3] patient participation in decision-making processes,[4–6] and the provision of information.[7,8] Evidence about the role of information with respect to decision making and informed consent is mixed. Some researchers found that giving patients more information and more time to arrive at a decision were associated with increased patient anxiety and lower consent rates.[9–11] Other researchers reported, however, that providing additional information did not affect anxiety levels in either control or intervention groups.[12] Yet, patients exercising autonomous decision making may take into account emotions, values, social norms, environmental barriers, and financial limitations, in addition to factual information.[13]

Researchers have long questioned the assumption underlying informed consent regulations, i.e., that patients take a rational and objective approach to medical decision making.[14] To understand the decision making process of seeking care at a U.S. cancer referral center and the association of that decision to informed consent, a qualitative study was conducted to obtain the perspectives of cancer patients and their caregivers.

Participants and Methods

Setting and Sample

Data were collected from a convenience sample of patients seen at a cancer clinic, located in the northwest United States, where approximately 550 people are treated with hematopoietic cell transplant (HCT) each year. All participants had to speak English and be 18 years of age or older with a Karnofsky Score of >80%. Patients also had to have consented to enroll in a Phase II HCT clinical trial. Each of the clinical trials involved early stage clinical research (haploidentical transplants, cord blood transplants, and tandem transplants) and so represented high-risk clinical research evaluating the safety of the respective procedures. These Phase II trials were examining outcomes related to engraftment, durability of engraftment, incidence and severity of graft versus host disease, and associated morbidity and mortality. Following study approval by the institutional review board, clinical staff assisted in identifying potential eligible candidates. An investigator explained the study to each candidate and consent to participate was obtained. At the time of consent, study patient participants were asked to identify one primary caregiver. These caregivers were then contacted and asked if they were willing to participate in the study.

Study Procedures

The study period spanned approximately one year, starting with a semi-structured interview before HCT (Time 1), followed by two additional interviews, with one conducted at approximately 80 days after HCT (Time 2), and the last 12 to 18 months after HCT (Time 3). Initial interviews were conducted by the investigators in a private setting in the clinic. Follow-up interviews at 80 and 365 days post-HCT were conducted either in the clinic or via the telephone (for those participants not returning to the clinic for follow-up appointments). At the initial interview, each patient and caregiver were asked, “How did you (or the person

you are caring for) end up at this clinic?" Follow-up questions were asked to probe more deeply into the details of the decision-making process, including "When did you make the decision to participate in the clinical trial?" "Who or what influenced your decision?", and "Who do you see as the primary decision maker?" Interviews conducted at Times 2 and 3 asked additional questions about decisional regret and usefulness of the Phase II study informed consent document. All interviews were tape-recorded and lasted approximately 1 hour or until no new information was heard. Recordings were transcribed and accuracy of the transcription was checked against the original recordings by one of the investigators (author's initials).

Data Analysis

Qualitative content analysis was the guiding research approach since this form of analysis deeply examines language within large areas of text, and then condenses the text into manageable categories.15 Shared understandings and meanings are represented in the created categories. Conventional content analysis was the particular form of analysis used for this study. In this method, researchers immerse themselves in the data and allow categories, themes, and insights to emerge, rather than approaching the text with some set of prescribed categories in mind.16 Interview transcriptions were entered in the qualitative analytic software program HyperResearch. Words, phrases, and sentences determined to be germane to developing themes were identified in the transcribed interviews. These units of analysis were then organized into common patterns and groupings based on their similarities. These categories were arranged into themes that answered the study's aim of describing patients' and caregivers' perspectives on cancer clinical trial decision making.

Results

Participant Characteristics

Twenty-five patients treated with HCT and 20 primary caregivers participated. Their ages ranged from 22 to 69 years, with a mean age of 54 years; 24 were women and 21 were men (Table 1). Lymphoma was the most frequent diagnosis (n=8; 32%; Table 1). Two patients (8%) died before day 80 (Time 2), while 2 others were too ill to be re-interviewed at day 80. At the Time 3 follow-up interview, an additional 8 patients had died, 1 had withdrawn from the study, and 2 others could not be contacted. Thus, a total of 10 patients (40%) had died by day 365. At Time 1 (before HCT), 5 caregivers declined study participation. At Time 2 (day 80), 15 caregivers were interviewed, and at Time 3, 6 caregivers were interviewed. A caregiver was not re-interviewed if his/her patient had died.

Major Themes

Data about decision making were categorized into three principal themes: "Steps in decision making," "Reasons for deciding," and "Elements of informed consent."

Steps in decision making

Patients and caregivers described who, when, and where they made their decisions regarding research participation. The timing and location of the decision occurred in one of two ways. For some (n=18 patients; 72%; n=12 caregivers; 60%), the decision rested upon the recommendations of their referring oncologists, and the decision happened long before they had consulted with oncologists at the research center. These decisions often were made in locations geographically distant from the center, such that the patients and their caregivers arrived at the center fully intending to participate in any options that were offered (Table 2).

Other patients traveled to the research center to consult with an oncologist and made the decision to stay for care by the conclusion of the consultation or very shortly thereafter.

Most patients (n=23; 92%) and caregivers (n=15; 75%) agreed that the decision to pursue any offered option was made before receiving any information provided in the informed consent conference (Table 2).

Reasons for deciding

When asked to articulate the reasons for deciding to seek care at a cancer referral center, the most frequent reason was that patients (n=15; 60%) and caregivers (n=5; 25%) felt that they had “no options” or “no choice” if they wanted to extend life. Thus, with a disease that could not be cured by standard therapy and with the view that death in the near future was not acceptable, the only “choice” was the one that offered the possibility of cure. Even though the “choice” entailed a clinical trial, these participants felt that the decision was an easy one to make.

For others, particularly for those who spent at least a year dealing with their disease, the decision was more difficult. Many patients with long-term diagnoses had been given conventional therapy, but they came to the center because the disease became resistant to conventional treatment. As one man explained: “we weren't looking for a study, because we had talked to NIH [National Institutes of Health] back in '96 or so, when I was first diagnosed, and they had all kinds of studies going, but I just didn't--at that point, their results weren't good and I didn't need it. So, I've been kind of dragging my feet all along waiting for technology to catch up with my disease.”

The disease process itself influenced the alacrity and apparent ease or not with which decisions were reached. Repeatedly participants talked about chemotherapy as being a temporary solution and indicated that transplant offered the only hope for a cure. A young woman diagnosed with Non-Hodgkin’s Lymphoma explained, “I want a cure. I don’t want to go home to die.” Cure was the single reason most frequently cited by patients (n=19; 76%) for deciding to participate in a HCT research study; 8 caregivers (40%) also identified cure as the primary motivation (Table 2).

Four patients also identified altruism as another reason to participate in research. Even if the transplant did not provide a cure or extend life, science would gain important knowledge from their participation, thereby benefiting future patients. As one woman noted when asked about providing consent for various clinical trials, “I said, ‘sure.’ That’s partly why I’m here too, you know. I’ve got good treatment and I wanna give back too.” Thus, for some, the desire to ensure cure of his/her own disease was accompanied by the altruistic motive of helping future patients.

Elements of informed consent

Respect for autonomy is an essential element of the informed consent process and entails three elements in decision making. To be autonomous, a decision must be intentional, made with understanding, and free from the undue influence of medical staff.17 With respect to the first and third elements of autonomous decision making, all patients in this study reported that their decisions were intentional, with 24 (96%) identifying themselves as the primary decision maker. The one patient who did not see himself as the primary caregiver was airlifted to the cancer clinic within a few days after the initial diagnosis of acute myelogenous leukemia and believed any decisions were solely that of the attending oncologist. None of the patients or family members identified any outside controlling influences governing their decision making.

In keeping with the second element of autonomy, patients gained understanding through many avenues, including referring physicians, family and friends. Even when patients discussed how there was *no* decision to make, they did consult with family members and

their physicians. One patient stated “You know, the family really wanted me to do it. The kids and my wife—and they wanted me to do it.” Similarly, another patient, a woman who had teen-age children commented, “I feel like that I would be quitting [if she did not seek further care] in the middle of what I made. … I’ve created this family that is very close and if I was just to--I’d feel like I was just quitting.” In each case, the decision to participate in a clinical research study gave patients a course of action that allowed them to potentially attain the desired goals of maintaining family relationships, of being present in the lives of loved ones, and of finding a cure for the hematologic malignancy that currently threatened their lives.

Consent forms can be an important dimension for offering understanding to people making complex decisions. When asked if they ever went back to re-read the consents they had signed upon arrival to the cancer referral center, 18 of the 21 participants (72%) interviewed at Time 2 stated they did not re-read the consents. One did not comment on whether she did or not, but noted that the consent forms were “overwhelming.” Five individuals (24%) stated that they did re-read their consents, with one noting, “I was curious about what I had agreed to.” One patient remarked that he “skimmed” the consent forms at the initial consenting conference, while two other patients admitted that they signed the consents without reading them (Table 2).

Additionally, several patients commented that they deliberately chose to *ignore* some of the information provided to them. One woman explained the information given to her before her consent conference included “every medicine, and every side effect and every consequence and every possible this, that, and the other. And it was just exhausting, and it was just scary.” She decided she was not going to pay attention to “all that nonsense” and she would “deal with it” if any of the risks became a reality. These findings underscore the complexity of the decision making process participants experienced.

Discussion

The three themes presented highlight the complexity of a decision to participate in a potentially life-saving research study. Accepted criteria for evaluating informed consent include having the capacity to decide, disclosing relevant information, understanding the disclosure, acting voluntarily, and granting permission.18 These elements are seen as encompassing the concept of autonomy and are essential components for the ethical conduct of research.

Findings from this study diverge from present-day decision making models that depict research/clinical trial participation decisions as single events (usually at the time when the consent is signed) based on providing adequate cognitive information. The rational/informational domain encompasses provision of information and understanding, while the contractual/signatory domain encompasses clinical decision making and formal documentation of informed consent. Both of these domains rely upon the cognitive processes of the person deciding to enroll in research clinical trials.

The rational/informational model has the appeal of providing information that promotes respect for autonomy as opposed to paternalism, since the patient makes the decision whether or not to participate supposedly based on “information”. Participation in clinical trials, however, often entails multiple decisions regarding possible courses of action, and rarely is all the necessary information available at the initial encounter. Additionally, individual and contextual factors can be ignored, including affective responses which play an important role in determining clinical trial participation.19 Focusing on improving the communication of information in the consenting process may be misguided. For example, a

short training program geared to improve the communication skills of oncologists in obtaining informed consent yielded little success.20

The majority (92%) of patients made their decision to participate in transplant research *before* they arrived at the center without the information about the specific study and *before* they actually had the consent conference and consent documents for the specific study in which they ultimately enrolled. That many participants (72%) never referred back to the informed consent document—with some admitting to never reading the document to begin with—points to the notion that information perhaps, is in fact not the most important consideration for some individuals. Continued efforts to increase patients' knowledge might serve little purpose for individuals who prefer to remain "ignorant" of particular information21 and raise important questions about the documents themselves, as well as the timing of when these documents are provided to patients.

From participants' perspectives, decision making was a multi-dimensional process including, but not limited to the mandated informed consent event and documents. As Little and colleagues22 observed in their study of 10 bone marrow transplant patients and their caregivers, the informed consent document can never provide enough information that will effectively convey the experience of going through such intense and risky therapy. Dresser agreed, noting that clinical trial documents and consultation meetings are inadequate in providing patients a realistic understanding of the consequences of decisions made.23 Thus, the present-day practice of focusing on information is inherently inadequate.

Study Limitations and Strengths

Study limitations include utilization of a convenience sample; interviews were not conducted with patients who decided to pursue other options, including those who decided to let the disease run its course without further medical intervention. Also, the sample lacks diversity in terms of participants' race/ethnicity and so limits its representation of the general U.S. population. The major strength of this study is that it followed participants over an extended period of time following HCT.

Conclusion

These findings add to the body of literature challenging the notion of using the rational/informational model of decision making as the sole vehicle through which informed consent is addressed. As McCaul and his associates24 pointed out, the informed decision making approach appeals because it appears to satisfy consenting requirements of patient autonomy, yet this approach may not culminate in the best decisions. Since 92% of all patients in this study reported making the research participation decision prior to informed consent conferences, perhaps the opportunity for dialogue about high-risk clinical trials consent conferences ought to occur *before* people travel to cancer referral centers.

The seriousness of the hematologic diagnosis and the high risk of death from the disease and/or the HCT itself create an ethical imperative beyond the provision of information. The discussion among cancer providers, researchers, and patients must not only be driven by regulatory mandates of providing cognitive "information", but also must reflect the intense emotional component active in the decision-making process. The relegating of informed consent to a linear cognitive process denies the reality of decision making. The increased risk posed by disease diagnosis and the high morbidity and mortality of the research HCT *can be* discussed with patients. In consent discussions, providers and researchers must recognize that patients' sense of "no option" is directly linked to the risk of dying. Death is not only a statistical component for patients' decision making; it is the back drop against which research protocol participation is considered. We need not change the offering of

information and the explanation of scientific reasoning in consent conferences. We must, however, also allow for the expression of the depth of the emotion and perception of risk that influences people "who have already decided what they intend to do."

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Table 1

Participants' Demographic Characteristics

Participants (n=45)		
Characteristic	**No.**	**%**
Sex (patient)		
Male	14	56
Female	11	44
Sex (caregiver)		
Male	7	35
Female	13	65
Race (patient)		
White	20	80
African American	1	4
Hispanic/Latino	1	4
Native American	2	8
Asian	1	4
Race (caregiver)		
White	18	90
African American	1	5
Hispanic/Latino	0	0
Native American	0	0
Asian	1	5
Age (patient)		
Range	22–69	
Age (caregivers)		
Range	35–62	
Diagnosis		
AML	6	24
Acute pro-mylocytic leukemia	1	4
Lymphoma	8	32
Hodgkin's	1	4
Multiple myeloma	5	20
Refractory anemia	3	12
Chronic lymphocytic leukemia	1	4

Table 2

Patient and Caregivers' Reasons for Deciding to Participate in Cancer Clinical Research

Theme (n=3)	Elements of theme	Patient (n=25)	Caregiver (n=20)	Sample Quotes
1. Steps in Decision Making	**Who**: Referral physician who made original diagnosis of malignancy.	n=18 72%	n=12 60%	• "Dr. ….just was absolutely clear as a bell about everything. So I was enthused…Let's go forward with [the transplant]." • "…so my doctor was like, well you may need a stem cell transplant, blah, blah, blah. We're sending you over to the …. clinic. So really, I had no choice."
	When: Decision to participate in clinical research made prior to arrival at cancer center consent conference.	n=23 92%	n=15 75%	• "It was the day we got my diagnosis… with my local doctor that we knew what we were going to do." • "We came out really to solidify the decision that I had already made."
2. Reasons for Deciding	**No Option:** Perception that conventional therapy held no further efficacy for the patient.	n=15 60%	n=5 25%	• "No brainer. It was the only viable option." • "No, it wasn't any decision. It had to be done. There was no choice. Only six feet under, probably."
	Cure: After induction and consolidation therapy, finding a permanent "cure" was desired.	n=19 76%	n=8 40%	• "But, you know, the deciding factor was, and I had to come to grips with it--at least this is a chance. Although it's a small chance, but it is a chance that … I can be cured." • "I want to be cured. The beauty of this transplant is the CLL could be cured."
3. Elements of Informed Consent	**Primary Decision Maker**: Patient identified as decision maker.	n=24 96%	n=19 95%	• "…[the decision was] squarely on my shoulders**."** • "I've pretty much always felt it was my decision."
	Re-reading Consent Forms: Did not review consent forms	n=18 72%	n=7 35%	"I'm gonna throw all the consents away and I'm gonna throw all the information away. I'm tired of lookin' at it. I never read it, you know."