

Study Seeks Understanding of Patients' Decisions to Enroll In Clinical Trials

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Recently, Drs. Kathleen Shannon-Dorcy and Denise Drevdahl, affiliate investigators in the Clinical Research Division, conducted a qualitative study to understand the motivation and decision making process of patients and their families who participate in clinical trials focused on the effectiveness of hematopoietic cell transplants (HCT). The authors interviewed 25 patients enrolled in phase II HCT trials at a cancer referral center, as well as the patients' primary caregivers. The phase II trials involved high-risk research to evaluate engraftment durability, incidence and severity of graft-vs.-host disease, and treatment-associated morbidity and mortality. Interviews focused on the process of patients' decision making, reasons for participation and elements of informed consent.

Among patients and their caregivers, 92% and 75%, respectively, had chosen to participate in clinical trials before receiving any specific information provided during a consent conference. For most participants, the choice was based on a recommendation from their primary care physician or resulted from an initial clinical consultation at the cancer referral center. The most frequent reason patients participated was that they felt they had little hope of extending life with current standard of care treatments. In contrast to conventional chemotherapy, HCT offered the best hope for a cure of their cancer, a point that particularly resonated among those with young families and those whose previous treatments were ineffective. Four patients also admitted to having altruistic hopes that their participation might further science and benefit future patients.

The process of informed consent in medical decisions is built upon the premise that patients are informed of, and understand the potential benefits and risks of, their treatment. This process also assumes that patients are capable of making the best decision based on this information. However, the authors found that although most patients and caregivers agreed that the patient was the primary decision maker, participant commitment to comprehending treatment risks and benefits was low. For example, only 24% of patients reviewed consent documents on their own to better understand the study's risks, benefits and involvement. Furthermore, several patients deliberately avoided this information because they deemed it too complex, exhausting or scary. Thus, some patients decided to participate in clinical trials prior to the provision of full information regarding the future effects and complications related to research participation.

Current trial standards focus on the provision of information to patients and patient-physician communication during consent conferences. However, the results of this study suggest that these standards may be inadequate and that information conveyed earlier and through alternate methods could be more effective, allowing patients and caregivers to reach a more rational decision.

[Shannon-Dorcy K, Drevdahl DJ](#). 2011. "I had already made up my mind": patients and caregivers' perspectives on making the decision to participate in research at a US cancer referral center. *Cancer Nursing* 34: 428-33.



Clinical Research Division's Kathleen Shannon-Dorcy (left) was the first author on the studies.