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Searching for a Way to Live to the End: Decision-Making Process in Patients Considering Participation in Cancer Phase I Clinical Trials

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Patients enrolled in cancer phase I clinical trials have advanced cancer, and no other standard treatments are available for them. Their cancer is end stage; the overall survival time of patients enrolled in a phase I trial is about 5–9 months (Bachelot et al., 2000; Han et al., 2003). Although patients who participated in phase I trials were aware of their option to decline and understood the risk of toxicities (Agrawal et al., 2006), a reason for participation was to obtain a possible health benefit (Agrawal et al., 2006; Cheng et al., 2000; Cox, 2000; Daugherty et al., 1995; Itoh et al., 1997; Meropol et al., 2003; Moore, 2001; Nurgat et al., 2005; Yoder, O'Rourke, Etnyre, Spears, & Brown, 1997). However, the primary objectives of most cancer phase I clinical trials are to evaluate the safety and toxicity of new medicines and to determine the maximum tolerated dose, not to assess therapeutic response. A recent review of cancer phase I trials reported an overall response rate to treatment of 10.6% and an overall toxicity-related death rate of 0.49% (Horstmann et al., 2005).

Wide disparity exists between patients' expectations and the objectives of studies; therefore, patients who consider participation in a phase I trial should carry out a thoughtful decision-making process. The decision-making process regarding participation in a phase I trial is a situation in which patients with end-stage cancer should assess whether they would be receiving an anticancer treatment with a low response rate and unknown toxicity.

Patients who had been invited but declined to participate in phase I trials have chosen to undergo only palliative care. Although carrying out strategies related to successful clinical trial participation is important (Lengacher et al., 2001), nurses should equally support patients who decline phase I trials and choose to undergo only palliative care. Whether or not to participate in a phase I trial is a significant decision that is associated with the patient's view of end of life. Therefore,

Purpose/Objectives: To reveal the decision-making process in patients considering participation in cancer phase I clinical trials.

Design: Grounded theory approach.

Setting: Cancer center in a metropolitan area of Tokyo, Japan.

Participants: 25 patients with cancer, including individuals who ultimately declined to participate in a phase I trial.

Methodologic Approach: Semistructured interviews and unstructured observations were conducted.

Main Research Variables: Patients' decision-making process and influencing factors.

Findings: The core category of patients' decision-making process was searching for a way to live to the end. The process consisted of four phases: only waiting for death to come if nothing is done, assessing the value of the phase I trial, finding decisive factors, and reminding oneself that this is the right decision. Factors influencing the process included patients' perceptions of physicians' explanations of the phase I trial, patients' perceptions of their families' attitudes toward the phase I trial, patients' experiences with past anticancer therapies, and patients' attitudes toward living with cancer.

Conclusions: Patient decision-making is a challenging process associated with issues about how to live at the end of life. The pattern of searching for a way to live to the end differed depending on the levels of the four factors that influenced patients' decision-making process.

Implications for Nursing: Nurses play pivotal roles in talking to patients about phase I trials, discussing what is important for the rest of their lives, and recognizing that patients made a satisfying decision for themselves.

supporting patients' decision making is an important role for nurses.

Few studies have examined the decision-making process of patients considering participation in cancer clinical trials. Schaefer, Ladd, Gergits, and Gyauch (2001)