Online Exclusive Article

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

Izumi Kohara, MSN, RN, CCRP, and Tomoko Inoue, PhD, RN

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.

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, 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)

reported that decision-making in women considering participation in a breast cancer prevention trial was a nonlinear, complex process that included reviewing one's life, wanting to be sure, chancing, and deciding. Madsen, Holm, and Riis (2007) found that women's decision-related experiences in participating in randomized clinical trials that included chemotherapy were a constant cautious balancing of personal options, searching for maximized effect, personal safety, trust, confidence, and being cared for. However, the authors assume that the decision-making process in patients considering participation in phase I trials differs widely in terms of psychological distress from the previous studies' patients. Unlike women in the previous studies, patients who are invited to participate in a phase I trial have cancer and do not have standard anticancer treatments.

Several studies referred to patients' decision making in phase I trials. Agrawal et al. (2006) assessed four areas of the decision-making process: knowledge of alternatives, pressure to participate, understanding the purpose and risks of the trial, and understanding the benefits. Agrawal et al. (2006) interviewed 163 patients who had consented to participate in a phase I trial and found that patients were aware of many alternatives to phase I studies; few patients experienced pressure from family or researchers; and many patients understood the purpose, risks, and benefits of the trial. Schutta and Burnett (2000) reported that the primary factors influencing patients' decisions to participate in phase I research were hope for a cure and trusting the oncologist's advice. However, no studies have examined the process by which patients decide to accept or decline participation in phase I trials.

Limited information exists on factors associated with patients' decision making regarding participation in phase I trials. Nurgat et al. (2005) reported that patients' decision making is influenced by their physicians and families; however, Agrawal et al. (2006) found that very few patients received pressure from their families and clinical researchers. Differences in factors that influence the decision-making process between patients who decide to participate in phase I trials and those who decline also are not clear. As a result, the current study aimed to reveal the detailed process of decision making in patients considering participation in a cancer phase I clinical trial and factors that influenced the process. This study also included patients who ultimately declined to participate in phase I trials.

Methods

Design

Patients' decision making in a clinical context is a complex and interactive process that is affected by three elements: the decision problem, the patient, and context (Pierce & Hicks, 2001). Decision making in the present study is making a choice to participate in a phase I trial or not, which would result from an interactive process including how the patient perceived information about the phase I trial, the patient's psychological status, and the patient's relationships with his or her physician and family. The grounded theory approach is useful for identifying social and contextual factors and the dynamic cognitive process in decision making (Pierce & Hicks, 2001).

The authors used the grounded theory approach (Strauss & Corbin, 1998) to reveal patients' process of decision making. The authors performed semistructured interviews and unstructured observations of patients who were invited to participate in a cancer phase I clinical trial.

Participants and Setting

Although theoretical sampling is important in the grounded theory approach, the number of patients who are invited to participate in a cancer phase I clinical trial is limited. Therefore, the investigators recruited all patients who were invited to participate in a phase I trial for an anticancer drug from February–November 2007 at a cancer center in the metropolitan area of Tokyo, Japan. Patients who had participated in other phase I trials were excluded. The current study was approved by the cancer center's institutional review board.

Procedure

After informed consent was obtained, unstructured observations of the participant's behavior and a semistructured interview were conducted during the time between being invited to participate in the phase I trial and starting any anticancer treatment. All data were collected in the outpatient clinic or in the participants'

- What feeling did you experience when a physician informed you about participating in a cancer phase I clinical trial (CPCT)?
- What do you think are the advantages of participating in a CPCT?
- What do you think are the disadvantages of participating in a CPCT?
- What feeling did you experience when deciding whether or not to participate in a CPCT?
- What are the reactions of your family members, friends, or colleagues regarding your decision?
- Is getting the opinions of your family member, physicians, or nurses helpful for you?
- How long did it take for you to decide whether to participate or decline to participate in a CPCT?
- What are the deciding factors in whether to participate or decline to participate in a CPCT?

Figure 1. Initial Interview Guide

unit at the cancer center. Unstructured observations were made when physicians informed patients about the phase I trial and when patients discussed the trial with their families. The observer paid close attention to patients' decision-making process and collected data from the discussions.

The investigators developed the initial guide for the interview (see Figure 1). The interviewer encouraged patients to talk about how their views and feelings on the phase I clinical trial changed over time. When new patients were interviewed, the interview guide was modified and new questions were added according to the properties and dimensions of categories from ongoing data analysis using theoretical comparison (Strauss & Corbin, 1998). Interviews lasted 20–76 minutes, were conducted in a private room, and were audiotaped and transcribed verbatim. Each participant was identified by a pseudonym. Three participants refused taping of the interviews; therefore, the investigators took notes while interviewing them.

The investigators could observe behavior in only six of 25 participants for a total of 110 minutes because the participants made few visits to the cancer center between the day of consenting to participate and the day of starting the next anticancer therapy. After observing each patient's behavior, the observer wrote a detailed description. Data were collected until no new categories emerged.

Data Analysis

An investigator collected data from patients' medical charts, semistructured interviews, and unstructured observations. The investigators confirmed patients' personal information (e.g., demographic characteristics, illness, history of cancer treatments) by reviewing each patient's medical chart. Demographic information from patients' medical charts was analyzed with descriptive statistics. Data from interviews and observations were analyzed according to the methods of grounded theory (Strauss & Corbin, 1998). The investigators split literal data using line-by-line coding after reading all transcripts and labeled them to express the contents of the split data. Similar labels were grouped and categories were organized with their properties and dimensions as open coding. Next, the investigators made correlations between categories and subcategories according to their properties and dimensions to explain the structure, process, and influencing factors of patients' decision making as axial coding.

Four phases emerged in the development of patients' decision-making process: the introduction phase, which was the patient's first reaction after being informed about the phase I trial; the development phase, when the patient viewed information about the phase I trial from a broad perspective; the turn phase, when the patient turned attention inward toward himself or herself; and the conclusion phase, when the patient made a decision. The investigators structuralized categories and subcategories using paradigms of situations, action or interaction, and consequences in each phase. Finally, the investigators integrated each category and extracted the core category to theorize patients' decision-making processes as selective coding. Simultaneously,

Table 1. Patient Characteristics

Characteristic	n	%
Age (years)		
Younger than 50	5	20
50–59	7	28
60–69	10	40
Older than 70	3	12
Gender		
Male	14	56
Female	11	44
Cancer diagnosis		
Colon	6	24
Lung	5	20
Breast	4	16
Head and neck	2	8
Renal	2	8
Esophagus	1	4
Pancreas	1	4
Biliary tract	1	4
Ovary	1	4
Liposarcoma	1	4
Thymoma	1	4
Months since cancer diagnosis		
Less than 12	7	28
12–24	8	32
25–36	4	16
37–48	–	–
49–60	2	8
61–84	1	4
85–120	2	8
More than 120	1	4
Previous chemotherapy regimens[a]		
1	5	20
2	4	16
3	5	20
4	8	32
5	3	12
Education		
High school graduate	8	32
Undergraduate degree	13	52
Unknown	4	16
Employment status		
Employed	7	28
Unemployed	6	24
Retired	7	28
Medical leave	5	20
Marital status		
Single	2	8
Married	19	76
Divorced	4	16
Living arrangements		
Lives with family	23	92
Lives alone	2	8

N = 25

[a] Excluding adjuvant chemotherapies

patterns of patients' decision-making processes were described with key properties. One investigator analyzed all data; the other investigator, who had much research experience using the grounded theory approach, validated the process of data analysis and the results. Trustworthiness of the data was addressed through close adherence to the method of grounded theory. Consensus about the process of analyzing data was reached through discussions between the investigators.

Results

Participant Characteristics

The investigators recruited 25 of 31 patients (81%) to participate in the current study (see Table 1). Six patients were excluded because they previously participated in other phase I trials or were withdrawn from consideration by the physician because of rapid progressive disease. All participants were Japanese. Median age was 60 years (range = 32–75 years) and median number of months since initial cancer diagnosis was 19 (range = 5–264 months). Of the 25 participants, 21 agreed to participate in a cancer phase I clinical trial (acceptors) and four declined (decliners).

Patients' Decision-Making Process

The core category that explained the entire decision-making process of patients considering participation in a phase I trial was searching for a way to live to the end. One patient described the decision-making process as, "I am walking on a fence. I will die if I fall on the right side, and I will survive if I fall on the left side." Another said, "I definitely won't stop anticancer treatments." The process consisted of four phases: only waiting for death to come if nothing is done, assessing the value of phase I trials, finding decisive factors, and reminding oneself that this is the right decision (see Figure 2). Each phase included several subcategories explaining the structure and process of patients' decision making (see Table 2).

Only waiting for death to come if nothing is done: The first phase of patients' decision-making process was described as, "Only waiting for death to come if nothing is done." The structure and process of the category were explained by six subcategories: learning that one has advanced cancer, understanding that no anticancer treatments exist other than phase I trials, realizing that no standard treatments exist despite having an advanced cancer, being confronted by the end of life, looking for the next move to make, and recovering from shock by looking for the next move to make. Major properties of this phase were patients' initial reactions after being informed about the lack of standard anticancer treatments, realization that the patient's own end of life and death are near with psychological shock, and starting to look for what to do next while recovering from shock.

> I had not imagined that the rest of my life consists of one-half year to a year. I was shocked because I unexpectedly realized that the rest of my life is short like so, when I was informed that there is no other standard cancer chemotherapy.

Assessing the value of phase I trials: The second phase was explained by the category "assessing the value of phase I trials." The patient recognized that he or she needed to decide whether or not to participate in a phase I trial, assessed risks and benefits (e.g., the possibility of therapeutic benefit and unexpected serious adverse events), looked for other options (e.g., complementary and alternative medicines) while fearing that no appropriate options exist, and realized that the decision would be made under uncertainty.

> I searched for information about my therapy on the Internet. I usually check the Internet. I become nervous if I don't search for information on the treatment because I take good care of myself.

Finding decisive factors: In the third phase, patients found factors to decide whether to participate in a phase I trial or choose only palliative care. Patients decided whether or not participating in a phase I trial is best after understanding the importance of their choice. Acceptors recognized that participating in the trial was a chance to live as long as possible and found decisive factors.

> I can abandon living. But it is also a terrible experience if I abandon living. So I take a gamble of having the possibility of living because I will suffer whether I am living or abandoning living.

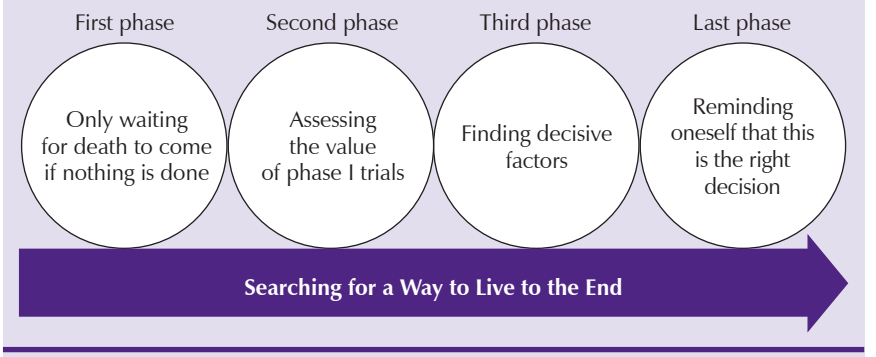

Figure 2. Decision-Making Process in Patients Considering Participation in Cancer Phase I Clinical Trials

However, decliners gave priority to doing what they wanted to do rather than anticancer treatments, including phase I trials.

> Previous cancer chemotherapies were not effective for me. So, I assume that the next chemotherapy will be less effective than previous therapies. . . . So, it is better for me to go where I want to go before it is too late.

Reminding oneself that this is the right decision: In the last phase, patients decided whether or not to participate in a phase I trial. Patients made the decision after preparing in the face of uncertainty and death in the future. Acceptors gambled on phase I trials, whereas decliners decided to end anticancer treatments. Neither acceptors nor decliners reflected on the past after making their decision. Acceptors ultimately lived with the hope of therapeutic benefit, and decliners challenged to live to the end without anticancer treatments.

> I only head toward the goal after deciding what my goal is. I know that my cancer is not curable. Although it would be wonderful if my cancer is cured by participating in a phase I trial, it is a dream.

Factors That Influenced Patients' Decision-Making Processes

The decision-making process in patients considering participation in phase I trials was influenced by four factors: patients' perceptions of physicians' explanations of the phase I trial, patients' perceptions of their families' attitudes toward the trial, patients' experiences with past anticancer therapies, and patients' attitudes toward living with cancer. The factors emerged as categories in the open coding and also were key properties of searching for a way to live to the end. The two main levels of each factor that influenced the decision-making process were set as positive or negative, or firm or not firm (see Table 3). In addition, four patterns of searching for a way to live to the end were identified based on the two main levels of the four factors. The patterns differed according to whether patients had a positive or negative perception of physicians' explanations of the phase I trial, whether patients had a positive or negative perception of their families' attitudes toward the phase I trial, whether patients had a positive or negative experience with past anticancer therapies, and whether or not patients had a firm attitude toward living with cancer (see Table 4).

Table 2. Subcategories of Patients' Decision-Making Process

	Paradigm		
Phase	**Condition**	**Action or Interaction**	**Consequence**
First	Learning that one has advanced cancer Understanding that no anticancer treatments exist other than phase I trials	Realizing that no standard treatments exist despite having an advanced cancer Being confronted by the end of life	Looking for the next move to make Recovering from shock by looking for the next move to make
Second	Deciding by oneself whether to participate in phase I trials Fearing that no next move to make exists	Recognizing phase I trials as experimentations Feeling that suffering disadvantages is unavoidable Fearing side effects Hoping for effectiveness of the new agent Comparing the new agent's data with those of previous therapies Searching for options other than phase I trials	Realizing the uncertainness of the outcome, even if one chooses what is best Being unable to decide easily
Third	Facing the importance of being burdened with uncertain outcomes Making a decision at any rate	Being able to tolerate anticancer treatments now[a] Finding reasons to justify the value of the phase I trial[a] Having an uncertain outcome, even if the drugs are approved[a] Wanting to live as long as possible[a] Realizing that the trial is a valuable option[a] Wanting to value one's own physical state[b] Giving priority to doing things that one likes to do over anticancer treatments[b]	Distracting attention from anxiety factors[a] Being ready for uncertain outcomes
Last	Becoming defiant toward decision making under uncertainty Estimating the rest of time until coming death	Gambling on a phase I trial[a] Ending anticancer treatments[b] Not reflecting on the past after making the decision	Living with hope toward the possibility of the new agent being effective[a] Challenging to live to the end without anticancer treatments[b]

[a] Described only by acceptors
[b] Described only by decliners

Table 3. Sample Quotations Regarding Factors That Influence the Decision-Making Process

Factor and Level	Quotation
Patient's perception of physician's explanation	
Positive	There was information about a good response for breast cancer in the consent form. It is valuable to try this therapy. I have heard that the adverse events are not terrible, although leukopenia was reported. So, I will participate in this trial. I know that it would be a waste not to participate in this trial.
Negative	My attending physician is supposed to recommend trying a new agent to test if it is truly effective. But I didn't feel that he recommended it when I heard his explanation about the agent. My impression was that every option is almost alike, so I thought it is enough and I will stop anticancer treatments.
Patient's perception of family's attitude	
Positive	My husband recommends that it is better to do everything I can. He expects that the new agent will be effective, although it may or may not be effective.
Negative	My wife commented that it is now time for me to give priority to do what I want to do and to go where I want to go, because my life will be limited by admissions to the hospital and frequent clinic visits if I participate in a trial.
Patient's experience with past anticancer therapies	
Positive	The side effects I had from previous chemotherapies were not as severe as those in other patients with cancer. I could work normally without taking sick leaves.
Negative	I had three cancer chemotherapy regimens. The side effects of those therapies were severe, especially in the last chemotherapy. Those situations are like one nail driving another. But the toxicities of anticancer drugs are too severe. Cancer chemotherapies may kill the human body.
Patient's attitude toward living with cancer	
Firm	It is a different story if the response rate of a cancer phase I clinical trial is 100% and I can live for decades. But the new drug is not that effective. So, now is a valuable time for me.
Not firm	How do people cope with cancer? I don't know what people with cancer do. I hesitate to make a decision, so now I have lost my resolve.

Patients' attitudes toward living with cancer were associated with whether they had hesitated or wavered prior to making the decision. For example, patients decided whether or not to participate in the phase I trial without hesitating or wavering if they had a firm attitude toward living with cancer. In contrast, patients hesitated or wavered before reaching a decision if they did not have a firm attitude toward living with cancer. Regarding the remaining three factors, patients who perceived their physicians' explanations of the phase I trial as positive and whose families had positive reactions toward the trial chose to participate even if their past experiences with anticancer therapies were negative. However, patients whose families had negative reactions toward the trial declined to participate even if they perceived their physicians' explanations as positive or they had positive experiences with past anticancer therapies.

Discussion

The current study revealed the detailed process of decision making in patients considering participation in cancer phase I clinical trials. Although two previous studies examined patients' decision making for participation in phase I trials (Agrawal et al., 2006; Schutta & Burnett, 2000), they did not describe the process of decision making and did not include patients who ultimately declined to participate. The current study included patients who agreed as well as those who declined to participate in phase I trials. In addition, the investigators observed that patients' decision making was a challenging process associated with issues about searching for a way to live to the end. Patients who were informed about phase I trials had psychological distress because of their awareness that no standard anticancer therapies existed for them and that they had to decide whether or not to participate in the trials on their own. Compared with previous studies that applied the grounded theory method to patients' decision-making process toward participation in a cancer prevention trial or a randomized cancer chemotherapy trial (Madsen et al., 2007; Schaefer et al., 2001), the process was harder for patients considering participation in phase I trials because they realized that the quality of the rest of their lives would differ greatly depending on whether or not they participated. Therefore, participating in cancer phase I clinical trials is a critical decision that greatly influences quality of life for patients with end-stage cancer.

Table 4. Patterns of Searching for a Way to Live to the End

Pattern	Factors That Influence Patients' Decision-Making Process			
	Perception of Physician's Explanation	Perception of Family's Attitude	Experience With Past Anticancer Therapies	Attitude Toward Living With Cancer
Gambling on a phase I trial without hesitation	Positive	Positive	Positive or negative	Firm
Gambling on a phase I trial after hesitation	Positive	Positive	Negative	Not firm
Ending anticancer treatments after wavering	Positive	Negative	Positive	Not firm
Ending anticancer treatments without wavering	Negative	Negative	Positive or negative	Firm

Accepting or Declining to Participate in Cancer Phase I Clinical Trials

According to the results of several surveys, the main motivation for patients to participate in cancer phase I clinical trials is having possible health benefits (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 et al., 1997). The tendency also was described in the current study as the subcategory "wanting to live as long as possible." Although an ethical concern about phase I trials is a poor-quality informed consent process (Agrawal & Emanuel, 2003; Joffe, Cook, Cleary, Clark, & Weeks, 2001), patients in the current study considered the risks and benefits of phase I trials and understood the uncertainness of the clinical outcome, as seen in the subcategories "feeling that suffering disadvantages is unavoidable" and "realizing the uncertainness of the outcomes, even if one chooses what is best." Participating in phase I trials was a way to live with hope and try everything possible for the accepters, similar to findings in previous studies (Moore, 2001; Schutta & Burnett, 2000).

Although a potentially small clinical benefit exists from participating in phase I trials, four patients (16%) in the current study declined to participate. The percentage is similar to the 21% (68 of 328) of patients with cancer who chose not to enroll in a phase I trial in a survey by Meropol et al. (2003). The small percentage may indicate that many patients tend to choose chemotherapy, even when experimental, near the end of life. However, the finding does not indicate that decliners' decision making was passive. Decliners chose their quality of life rather than anticancer treatments that have risks, as seen in the subcategories "wanting to value one's own physical state" or "giving priority to doing things that one likes to do over anticancer treatments." Acceptors as well as decliners performed active decision making because they had searched for a way to live to the end, as described in the core category.

Influencing Factors

Several studies referred to the influences of patients' trust in physicians (Agrawal et al., 2006; Daugherty et al., 1995; Itoh et al., 1997; Madsen et al., 2007; Nurgat et al., 2005; Schutta & Burnett, 2000) and their families (Agrawal et al., 2006; Daugherty et al., 1995; Itoh et al., 1997; Nurgat et al., 2005) in deciding whether to participate in phase I trials. In the current study, four factors were found to influence patients' decision-making process; patients' experiences with past anticancer therapies and attitudes toward living with cancer are new factors that were not detected in previous studies. In addition, the current study revealed that patients' decision making is a complex process with four patterns that differed according to the combination of the four factors.

Patients' attitudes toward living with cancer affect whether they can decide to accept or decline participation in cancer phase I clinical trials with or without hesitating or wavering. Although the influence of patients' families is similar to that found in previous studies of decision making, all patients' decisions were consistent with their families' attitudes in the current study. Patients may value the opinions and attitudes of family members who had experienced previous anticancer therapies with the patient.

Differences between acceptors and decliners in factors that influenced the decision-making process depended on combinations of the four factors. However, the influence of family's attitude toward the phase I trial may be stronger than the other three factors because no patients accepted or declined participation against their families' attitude.

Study Limitations

The current study was conducted at one cancer center in the Tokyo metropolitan area. Therefore, the health care provided to participants may have included practices particular to that cancer center. Regarding the theoretical comparative process, the investigators could not compare all combinations of the four factors as key properties and their level as dimensions. However, collecting data

on all combinations was not appropriate because the current study showed that hesitating or wavering on one's decision to participate in a phase I trial depended on the patient's attitude toward living with cancer. In addition, deciding whether or not to participate in a phase I trial depended on the level of the other three factors. Therefore, the investigators would not have found new patterns of patients' decision-making process if they had continued sampling.

Transferability of the current study is not complete because the investigators did not conduct theoretical sampling. However, recruiting all eligible patients who were invited to participate in a phase I trial could compensate for this study's transferability.

Future Research

Additional studies on nursing interventions in the decision-making process of patients considering participation in cancer phase I clinical trials are needed. The current study did not reveal how nurses support patients' decision making or the effects of intervention. The framework of interactive decision making (Pierce & Hicks, 2001) and the four phases found from the results of the current study may be useful in actual nursing interventions. In addition, research regarding how patients accept the outcome of self-determination is significant because the rest of their lives will be different depending on whether they participate in a phase I trial or choose palliative care only. Outcome acceptance is an important topic for understanding how patients actually live to the end of life.

Nursing Implications

Nurses can support patients' decision-making processes by focusing on the four phases found in the current study. The first phase is a time when patients face the hard reality of the lack of standard anticancer treatments. Appelbaum and Grisso (1988) referred to the function of patients' competence to make decisions; a patient's capacities might be low if he or she had strong psychological distress or a psychological crisis. Therefore, nurses should assess patients' psychological state and capacities during the initial phase. Healthcare providers should give patients sufficient time to make a decision until their psychological state recovers. If healthcare providers give information such as the purpose, risks, and benefits of a phase I trial to patients who have not yet recovered from psychological crisis, patients will not be able to understand the information correctly. Therefore, nurses should assess patients' readiness to absorb information effectively.

The second phase is when patients closely examine the risks and benefits of phase I trials and other options, such as complementary and alternative medicines. Although the purpose of phase I trials is mentioned explicitly in most trials' consent forms (Horng et al., 2002), several studies reported patients' misconceptions about cancer clinical trials (Barrett, 2005; Daugherty et al., 1995; Joffe et al., 2001). According to a systematic review by Flory and Emanuel (2004), person-to-person interactions such as an active nursing intervention (Aaronson et al., 1996) may be more effective in improving patients' understanding compared to using multimedia and enhanced consent forms. Nurses should discuss phase I trials with their patients to increase their understanding during the second phase.

During the third phase, patients clarify the way to live to the end. Patients cannot decide whether to participate in a phase I trial without clear decisive factors; therefore, nurses should encourage patients to clarify what is important for the rest of their lives with cancer. Individuals who consider participating in phase I trials are terminally ill patients with a short life expectancy, and a counseling strategy should be developed for them (Agrawal & Danis, 2002). Counseling by nurses would be helpful for patients during this phase. Patients will find what is important to them for the rest of their lives through meaningful discussion with nurses.

The last phase is when patients make their choice. Nurses should praise patients' efforts by saying that they have made a satisfying choice for themselves if they reached a decision as a result of carefully considering the value of the phase I trial and finding decisive factors while in a good psychological state. Patients can gain confidence in their own choice from nurses' assurances.

Healthcare providers might be able to predict a patient's choice by noticing the following factors. Patients will decide to participate in phase I trials without hesitation if they perceive physicians' explanations of phase I trials as positive, their families' attitudes toward phase I trials are positive, their experiences with past anticancer therapies are positive, and they have a firm attitude toward living with cancer. By focusing on the factors, nurses can better assess whether or not patients will choose to participate or feel pressure from physicians or their families.

Decliners do not visit clinics as often as acceptors, and healthcare providers may not spend as much time with them as with patients considering participation in phase I trials who meet performance status eligibility criteria. Decliners challenge to live to the end of life without anticancer treatments; therefore, nurses should continuously help patients realize their preference.

Conclusion

The decision-making process in patients considering participation in cancer phase I clinical trials is a challenging experience for those facing issues about how to live to the end life. Patients must decide whether they will gamble on the possibility of the new agent being effective or choose to receive only palliative care. The

process consists of four phases and is influenced by four factors. Nursing interventions according to that process and assessing the influencing factors must be effective to improve support for patients' decision making.

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Izumi Kohara, MSN, RN, CCRP, is a doctoral candidate and Tomoko Inoue, PhD, RN, is a professor, both in the Graduate School of Health Care Sciences at Tokyo Medical and Dental University in Japan. This study was supported by a grant from the Pfizer Health Research Foundation in Japan. Kohara can be reached at ikohara@jichi.ac.jp, with copy to editor at ONFEditor @ons.org. (Submitted October 2008. Accepted for publication May 25, 2009.)

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