

Factors and Outcomes of Decision Making for Cancer Clinical Trial Participation

Barbara A. Biedrzycki, PhD, CRNP, AOCNP®

The Institute of Medicine (2002), in its report *Responsible Research: A Systems Approach to Protecting Research Participants*, stressed the need for empirical data to evaluate satisfaction with the decision to participate in research. Individuals with advanced cancer may be particularly vulnerable when deciding to join a cancer clinical trial. Although patients with advanced cancer may appropriately decline to participate in clinical trials after weighing the risks and benefits in light of their own values, many have expressed confusion concerning this decision. For example, some individuals joined cancer clinical trials expecting a therapeutic benefit when the purpose of the study was limited to testing for toxicities (Daugherty et al., 1995; Kass, Sugarman, Faden, & Schoch-Spana, 1996). Others declined to participate in therapeutic clinical trials, citing an overwhelming fear of their cancer and limited understanding of the study (Stevens & Ahmedzai, 2004) and decisional conflict (Flynn et al., 2008). A systematic review of patient education revealed that multimedia approaches were ineffective in promoting better patient understanding of clinical trial options or satisfaction with the decision to accept or decline participation in a cancer clinical trial (Flory & Emanuel, 2004).

Many factors may affect satisfaction with the decision to join a cancer clinical trial. Most research participants believe they are helping future patients and contributing to science (Moore, 2001). Potential cancer clinical trial participants declined because of fear of their illness and limited understanding of research and then later regretted not joining the trial (Stevens & Ahmedzai, 2004). More information is known about satisfaction with standard treatment decisions than research decisions. For example, dissatisfied people with cancer did not regret declining an alternative treatment, but rather were dissatisfied because they did not take a more active role in treatment decision making (Hack, Degner, Watson, & Sinha, 2006). Decisional regret can have a long-term effect on quality of life (Clark, Wray, & Ashton, 2001).

Satisfaction with the decision to participate in a cancer clinical trial and actual accrual to cancer clinical trials

Purpose/Objectives: To describe factors and outcomes related to the decision-making process regarding participation in a cancer clinical trial.

Design: Cross-sectional, descriptive.

Setting: Urban, academic, National Cancer Institute–designated comprehensive cancer center in the mid-Atlantic United States.

Sample: 197 patients with advanced gastrointestinal cancer.

Methods: Mailed survey using one investigator-developed instrument, eight instruments used in published research, and a medical record review.

Main Research Variables: Independent variables: disease context, sociodemographics, hope, quality of life, trust in healthcare system, trust in health professional, preference for research decision control, understanding risks, and information. Dependent variables: decision to accept or decline research participation and satisfaction with this decision.

Findings: All of the factors within the Research Decision Making Model together predicted cancer clinical trial participation and satisfaction with this decision. The most frequently preferred decision-making style for research participation was shared (collaborative) (83%).

Conclusions: Multiple factors affect decision making for cancer clinical trial participation and satisfaction with this decision. Shared decision making previously was an unrecognized factor and requires further investigation.

Implications for Nursing: Enhancing the process of research decision making may facilitate an increase in cancer clinical trial enrollment rates. Oncology nurses have unique opportunities as educators and researchers to support shared decision making by those who prefer this method for deciding whether to accept or decline cancer clinical trial participation.

both are important outcomes of decision making. Therefore, the purpose of this study was to examine the factors and outcomes of decision making for cancer clinical trial participation. The specific aims of this study were (a) to examine the relationship between disease context and sociodemographic factors to patient preferences for research decision control and (b) to identify significant factors that influence the decision to join a cancer clinical trial and the satisfaction with this decision.