Decision Making for Cancer Clinical Trial Participation: A Systematic Review

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Purpose/Objectives: To describe what is known about the factors that influence cancer clinical trial decision making.

Data Sources: PubMed database and reference lists of identified articles.

Data Synthesis: Variations in research design and methods, including sample characteristics, instrumentation, time between decision made and measurement of decision making, and response rates, have effects on what is known about decision making for cancer clinical trial participation. Communication, whether in the form of education about a cancer clinical trial or as a personal invitation to join, is an important factor influencing decision making. Personal and system factors influence the outcomes of decision making for cancer clinical trials.

Conclusions: The process of decision making for cancer clinical trials is understudied. Nevertheless, the currently available cancer clinical trial decision-making literature suggests a multitude of factors that influence the outcomes of the decision to accept or decline clinical trial participation, as well as the psychosocial consequences of decisional regret, pressures, and satisfaction.

Implications for Nursing: The decision-making process of cancer clinical trials is a fertile area for research and, subsequently, evidence-based interventions. Oncology nurses are in a position to facilitate the process and to relieve the pressures patients perceive regarding decision making for cancer clinical trials that will benefit individuals and, ultimately, society.

Increased participation in cancer clinical trials would benefit individuals with cancer and society by contributing to the understanding of the effects of new cancer treatments on patient outcomes (American Cancer Society, 2009; National Cancer Institute, 2009). Limited literature indicates that the process by which patients decide to join or decline participation in a cancer clinical trial is poorly understood. This systematic review attempts to identify the factors that influence clinical trial decision making among patients with cancer by critically evaluating relevant studies. Better understanding the decision-making process may help clinicians identify ways to improve patient-provider communication, possibly leading to increased clinical trial participation. Furthermore, such information may provide opportunities to create interventions to facilitate decision making and benefit the person with cancer as well as society.

Background

Considering just the interest of society, enhanced rates of participation in cancer clinical trials should not only hasten the testing and development of effective treatments, but also save cost and energy by discounting ineffective treatments more efficiently. For people with cancer, participating in clinical trials provides access to research with the hope of extending survival time, greater access to healthcare professionals, and altruistic satisfaction.

Tejeda et al. (1996) first reported a frequently cited historical estimate of cancer clinical trial participation of less than 3%. More recent studies have reported enrollment fraction, a value comparable to cancer clinical trial participation rate, as low as 1.7% (Murthy, Krumholz, & Gross, 2004) and 0.68% (Stewart, Bertoni, Staten, Levine, & Gross, 2007). Cancer clinical trial participation varies by cancer diagnosis: for example, 3.2% in breast cancer and 0.8% in prostate and lung cancers (Murthy et al., 2004).

Several patient and system barriers to clinical trial participation have been identified, including access, perceived harm, quality of life, and diversity. Limited access to clinical trials may be related to a lack of awareness, as well as physical and financial obstacles.

A common misconception exists that cancer clinical trial participation is harmful (Epstein & Street, 2007). In fact, studies have suggested a favorable risk-benefit ratio when patients with cancer consider a phase I cancer clinical trial compared with nonvalidated therapies in which the risks may be known but the benefits unknown (Joffe & Miller, 2006; Horstmann et al., 2005; Kurzrock & Benjamin, 2005).

Most (93%) phase I cancer clinical trial research participants indicated that their quality of life was at least as important as their length of life (Meropol et al., 2003).