

Quality of Informed Consent: Measuring Understanding Among Participants in Oncology Clinical Trials

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Purpose/Objectives: To describe newly enrolled clinical trial subjects' knowledge and understanding of the oncology clinical trials in which they were participating.

Design: Descriptive, correlational.

Setting: The oncology center of a small community hospital in New England.

Sample: 8 patients who consented to enroll in oncology clinical trials.

Methods: The Quality of Informed Consent questionnaire was sent to 17 potential participants who recently had consented to participate in oncology clinical trials.

Main Research Variables: Knowledge of the basic elements of informed consent and participants' understanding of the clinical trials in which they were enrolled.

Findings: Scores on the Quality of Informed Consent questionnaire indicated that participants had a good overall understanding of the basic elements of informed consent as well as the clinical trials in which they were enrolled. However, half of the sample failed to understand that clinical trial treatment is not standard treatment and may involve additional risk when compared with standard treatment.

Conclusions: The results of this investigation provide valuable feedback regarding participants' understanding of the informed consent process. The Quality of Informed Consent questionnaire may be a useful tool for monitoring the quality of the informed consent process and contributing to patients' understanding of clinical trials and the research process.

Implications for Nursing: The Quality of Informed Consent questionnaire may provide valuable feedback regarding clinical trial participants' understanding of clinical trials and the research process. Individual responses to questions on the questionnaire may be used to aid personalized patient education and validation of the informed consent throughout trial enrollment. Future research efforts need to focus on the development of reliable tools to measure participants' understanding of informed consent and nursing interventions that improve the informed consent process as well as enhance patients' understanding of the research process.

Clinical research is a necessary step in the process of translating scientific discovery and technical advancement into procedures and products that offer the prospect of a better life (Koski, 2000). Along with the potential benefits of clinical research come ethical and legal obligations to protect the rights of human participants. Informed consent is one way participants' rights are protected in clinical research. Grounded in the ethical principles of autonomy, beneficence, and justice, a valid consent can be conceptualized best as a communication process (Daugherty, 1999) in which an exchange of information takes place between a patient or

Key Points . . .

- ▶ Current methods of obtaining valid informed consent from potential participants in oncology clinical trials may be insufficient to ensure patients' understanding of information about the proposed trial.
- ▶ The ability to assess individuals' understanding is essential to ensure the validity of the informed consent process.
- ▶ The Quality of Informed Consent questionnaire may be a useful tool for assessing and enhancing patients' understanding of clinical trials.
- ▶ Nurses are challenged to develop strategies that provide clinical trial patients with a better understanding of the clinical trial they are considering, identify areas of misunderstanding and correct them, and assess the outcomes of the informed consent process.

participant and a clinician or investigator regarding an investigational or experimental treatment. To give genuine informed consent, potential participants must have access to sufficient, easily understood information and be given the opportunity to consider it thoughtfully and ask for clarification or additional information. Achieving this level of informed consent requires more than just acquiring a participant's signature (Sharp, 2001; Stiffler, 2003).

Several issues relate to obtaining true informed consent from individuals considering participation in oncology clinical trials. Current methods of obtaining valid informed consent may be insufficient to ensure patients' understanding of information about the proposed trial (Daugherty, Kiolbasa, Siegler, & Ratain, 1997; Erlen, 2000; Yoder, O'Rourke, Etnyre, Spears, & Brown, 1997). In addition, the problem of therapeutic misconception may exist among participants. Therapeutic misconception is a phenomenon in which research participants deny the possibility that major disadvantages or risks to participating in clinical research

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