

Clinical Trials Research: Challenges of Patient Education and Informed Consent

Case Study

B.R. is an 83-year-old Norwegian woman with stage III papillary serous ovarian cancer diagnosed after she presented with a two-month history of abdominal pain and bloating. An ultrasound followed by paracentesis revealed a moderate to large amount of ascitic fluid, and cytology was positive for adenocarcinoma. An abdominal computed tomography scan demonstrated extensive peritoneal carcinomatosis, extensive ascites, a heterogeneous nodule of the left adrenal gland, and trace right pleural effusion. Cancer antigen-125 (CA-125) initially was elevated to 71 u/ml (normal < 35 u/ml) and rose to 7,399 u/ml preoperatively.

B.R. underwent an exploratory laparotomy with total abdominal hysterectomy and bilateral salpingo-oophorectomy, including omentectomy and appendectomy. Pathology revealed high-grade adenocarcinoma. On postoperative day four, B.R. was started on single-agent carboplatin (Paraplatin®, Bristol-Myers Squibb, Princeton, NJ) for a total of four doses followed by docetaxel (Taxotere®, Aventis Pharmaceuticals Inc., Bridgewater, NJ) for a total of five doses. After six cycles of chemotherapy, her CA-125 normalized to 10 u/ml but began to elevate during the next cycle. A computed tomography scan was ordered and confirmed progressive disease in the pelvis. At this time, B.R. was offered continued conventional chemotherapy or participation in a clinical trial (i.e., a phase II, open-label, multicenter study for patients with advanced, refractory, or recurrent ovarian cancer).

B.R. is a single, retired, master's-prepared teacher and librarian who resides alone in her home. She is proud of her independence and cares for herself, including cooking, cleaning, shopping, and engaging in an active social life. She enjoys participating in a weekly puzzle club, going to museums, and attending luncheons with friends.

When questioned about participation in a clinical trial, B.R. initially responded positively. She was confident in her physician's advice that a clinical trial was a good treatment option and hoped that she would be

cured. However, after reading the informed consent, B.R. was shocked with the stated inclusion criteria: "advanced ovarian cancer that continues to grow despite prior treatment." B.R. was distressed, stating that she did not realize the gravity of her illness until then. On further inquiry, B.R. articulated her understanding of clinical trials as "the thing to do with a rising CA-125" and that she was somewhat aware when presented with the option of a trial that the study drug would not "get rid of the tumor."

As part of initially educating B.R. about clinical trials research, the nurse investigated B.R.'s personal goals for participating, which included her hope to help science and herself. However, she expressed barriers to participation such as doubt about the treatment's effectiveness and the nuisance of visiting the cancer center for frequent blood draws. During B.R.'s participation in the clinical trial, she appreciated the extra attention she felt she received as a patient. Psychologically, she dealt with the challenges and side effects of treatment by maintaining her social relationships "to keep her mind busy and on other things." Unfortunately, B.R. left the study because of progressive disease. At follow-up, she told a nurse that she was scared and "went to pieces, calling another nurse for a sleeping pill" because she was unable to sleep at night as a result of her anxiety. However, she continued to express hope that she would be cancer free in the future and always would trust her doctor's judgment.

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Clinical Problem Solving

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What information regarding clinical trials research is best communicated to educate patients prior to signing an informed consent form?

Oncology nurses play a vital role in the support and education of patients enrolled in clinical trials, beginning by informing patients that clinical trials are designed to answer questions related to the safest and most effective treatments for cancer (Albrecht, Blanchard, Ruckdeschel, Coovert, & Strongbow, 1999; Lee, 2004a). Nurses who directly educate patients during the informed consent process must be knowledgeable about all components of consent, as outlined by the National Cancer Institute (Erikson & Kuck, 2001), including the risks and benefits of treatment as well as confidentiality and compensation for any injuries incurred. Patients must understand that their participation is voluntary and that their consent can be withdrawn at any time without retribution (Erikson & Kuck).

Nurses should be familiar with the types of clinical trials that are conducted to investigate conventional and complementary and alternative medicine treatments (Lee, 2004a) (see Table 1). Prior to signing an informed consent, patients should be informed about the study's application to their situation, the terminology related to clinical trials, and the study phase involved. With the proper educational preparation, nurses can avoid a scenario similar to B.R.'s. Being in the presence of a patient who expresses shock or distress when reading an informed consent form can be difficult for any nurse.

The solutions offered to the clinical problems posed in this column are the opinions of the authors and do not represent the opinions or recommendations of the Oncology Nursing Society, the Oncology Nursing Forum, or the editorial staff. (Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Society.)

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