

Therapeutic Misconceptions and Misestimations in Oncology: A Clinical Trial Nurse's Guide

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Therapeutic misconceptions and misestimations occur frequently in oncology clinical trials and can potentially compromise informed consent. Despite the increased awareness of these issues in medical literature, many practitioners and nurses continue to be unfamiliar with these concepts. This article will define therapeutic misconceptions and misestimations, explore contributing factors, and explain how they can be prevented by clinical trial nurses.

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A clinical trial nurse (CTN) has been asked to assist with the informed consent process for Mrs. S to participate in a clinical trial. Mrs. S recently was diagnosed with stage IV breast cancer. The physician has introduced and briefly described the trial to the patient. The CTN enters the room and sits down with the emotional patient and her family and asks what Mrs. S has been told about the trial. Mrs. S cries, states that she needs chemotherapy, and says that this treatment would be the best thing for her right now. The CTN questions her again by asking, "Why do you feel this is your best treatment option?" Mrs. S answers, "I know the doctor wouldn't offer me anything he didn't feel was best for me." The CTN replies, "I think you may have misunderstood some important facts about this option. Why don't we start over and allow me to explain what this trial entails and how it may differ from your other treatment options."

Mrs. S's belief that her physician would only offer treatments that will provide the best care is a symptom of therapeutic misconception. Therapeutic misconceptions happen frequently within oncology clinical

trials (Appelbaum & Lidz, 2008a). In a study of participants who enrolled in phase I oncology clinical trials, more than 68% of participants were experiencing a therapeutic misconception and 94% suffered from therapeutic misestimations (Pentz et al., 2012). When a therapeutic misconception occurs in a current or potential research participant, the informed consent may be compromised (Appelbaum & Lidz, 2008a). CTNs who understand therapeutic misconceptions and misestimations can prevent these from occurring by advocating for research participants, thereby increasing patients' understanding of the informed consent and trial.

Definitions

The term *therapeutic misconception* was first described by Appelbaum, Roth, and Lidz (1982). They reported that this phenomenon exists when research participants believe the care they receive on a clinical trial is based on their needs and is designed to benefit them personally (Appelbaum et al., 1982). This, however, is actually the basis of clinical care (Appelbaum & Lidz, 2008a), whereas the goal

of a clinical trial is to obtain generalizable knowledge to benefit future patients (Grady & Edgerly, 2009; Lawrence, 2008). Clinical, or personalized, care is medical care given to a patient designed specifically for that individual and tailored to their particular needs (Appelbaum & Lidz, 2008a). Care received through clinical trials may be structured, and the specific protocol may not allow adjustments in the regimen or specific medications given for side effects, which is contrary to clinical care (Appelbaum & Lidz, 2008a).

The concept of therapeutic misconception was first seen in randomized, controlled placebo trials and, over time, has been generalized to other forms of trials (Kimmelman, 2007). During the 30 years since this concept was first defined, many articles have been written and published within medical journals attempting to further refine this idea. Despite this, Appelbaum and Lidz (2008b) stated that little effort has been made in preventing therapeutic misconception from occurring.

Therapeutic misestimation is a related concept that differs in that the participant has failed to fully understand the estimated risks or benefits involved with the research (Hornig & Grady, 2003). When misestimations occur, patients may believe that a greater chance of personal benefit exists than what trial coordinators expect, or may fail to appreciate additional risks from trial participation. This occurs in phase I trials when the goals are safety, identifying toxicities, and determining maximum tolerated dose. For phase I trials, efficacy is not a primary outcome, and fewer than 5% of phase I oncology clinical trials involving an experimental medication have proven to provide benefit (Daugherty, 1999).

Therapeutic misconceptions and misestimations have the potential to negatively