Phase I Cancer Trial – Therapeutic Misestimation[1]

Category: Clinical Research, Basic Science

Roles:

- Research Investigator
- Cancer Patient
- Patient's Sibling

Background Information:

The research study has NIH funding to conduct a phase 1 trial of a new chemotherapeutic agent to treat colon cancer. The purpose of a phase I trial is to discover the maximum tolerated dose of the agent in humans. Participants in the trial are assigned randomly to dosage, which range from sub-therapeutic to high enough to cause potentially severe side effects. The agent is estimated to have less than 5% probability of even temporary benefit based on previous meta-analyses of similar phase I cancer trials. The risks of the untested agent exceed those of standard chemotherapy and the chance of severe adverse effect is probably much greater than 5%. The research is only used on those who have already tried standard chemotherapy with no success.

Research Investigator:

I am in the clinic recruiting patients and I interview a 45-year old journalist with advanced colon cancer who seems eager to enroll in the trial to assess his/her understanding of the research.

[1] These scenarios have been adapted from Horng and Grady, "Misunderstanding in Clinical Research: Distinguishing Therapeutic Misconception, Therapeutic Misestimation, & Therapeutic Optimism," *IRB*, Jan-Feb 2003, pp.11-16.

Cancer Patient:

I am 45-year-old journalist with advanced colon cancer interested in participating in the trial. I heard about it through my clinic and am now interviewing with the recruiter. I have a 10-year-old daughter. I have been treated with standard chemotherapy, but my cancer is still advancing. I believe that the purpose of the trial is to find the highest dose of the drug that is safe in humans, and has considered the possibility that I could be assigned either to a dose that is too low to have a therapeutic effect on my cancer or to a dose that is high enough to cause severe side effects. Nonetheless, I state that this is a "low risk research trial," and estimate the probability of benefit to be around 30%.

Patient's Sibling:

I am the patient's 38-year-old sibling and am present during the pre-enrollment interview. I am distraught at the thought of losing my sibling, and want my sibling to go ahead with the trial. Like my sibling, I estimate the probability of benefit to be around 30%.

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Imagine you are the potential participant and that you will need, at the conclusion of your exchange with the researcher, to decide whether or not to participate. Which decision you make is up to you.

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