Phase I Cancer Trial – Therapeutic Misestimation

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 I 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 Homg 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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