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Unrealistic Optimism in Early-Phase Oncology Trials

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Early-phase oncology trials are vital for developing new and more effective therapies for treating cancers. While it is possible that some of these trials provide benefit to patient-subjects,[1] it is widely recognized that early-phase trials are not designed to provide direct therapeutic benefit to those who participate in them. This reality has given rise to much ethical concern.[2] Why would patients agree to enroll in clinical trials that expose them to treatment interventions that offer relatively little prospect for direct therapeutic benefit? One possibility, much discussed over the past two decades, is that many patients fail to understand the nature and purpose of the research in which they agree to participate. This is the so-called therapeutic misconception.[3] Another often mentioned possibility is that patients enroll in early-phase cancer trials because they genuinely want to help researchers obtain scientific knowledge that might benefit future patients who suffer from the same disease.[4] A third range of possibilities recently has begun to receive more attention: expectations for benefit from early-phase oncology trials may simply reflect the fact that patients are hopeful or optimistic about their participation in these trials.[5] It remains unclear, however, what accounts for this optimism. Do optimistic expectations for benefit just reflect a disposition to think positively in difficult situations, or is something more going on? We investigated the possibility that optimistic expectations for benefit are tied to a bias that distorts, or has the potential to distort, how patients process information about the potential risks and benefits of clinical trials.

Our findings raise questions about a common assumption that many cancer researchers have about optimism. This assumption is the view that optimism presents no ethical problem for informed consent to participate in cancer research.[6] It is sometimes claimed further that

expressing optimism in the context of cancer research is a good thing.[7] Indeed, it has been suggested that optimism is an effective means for patient-subjects to cope with anxiety or ward off depression.[8] Yet as research in social psychology has revealed, optimism is a complex phenomenon. While it may reflect mere hopefulness and it may provide some psychological benefits, optimism may also be the product of a bias in which a person believes that she is more likely to experience positive outcomes (or less likely to experience negative outcomes) than others similarly situated. When optimism is the product of a bias of this kind, it is typically referred to as the "optimistic bias" or "unrealistic optimism." In the context of early-phase oncology research, unrealistic optimism may have negative consequences for behavior, and it may present an ethical problem for informed consent in clinical research.[9]

The Concept of Unrealistic Optimism

Unrealistic optimism, understood as a bias, has been extensively studied in social psychology. The optimistic bias has been found to be present in a wide range of health-related contexts in which people are presented with risks and benefits.[10] However, since the notion of unrealistic optimism may be unfamiliar to some readers, we now provide some background to the phenomenon.

Unrealistic optimism should not be equated with optimistic attitudes per se. Not everyone who is optimistic is unrealistically optimistic. Some people have a general positive outlook on life. This kind of optimism is often referred to as dispositional optimism. Since it refers to a general orientation, it is neither realistic nor unrealistic.[11] In contrast, unrealistic optimism is present with respect to specific events or hazards. A person can be unrealistically optimistic about some event without being dispositionally optimistic, and vice versa. With respect to a specific event, it is also possible for a person to believe accurately that he is more likely to experience a positive outcome or less likely to experience a negative outcome than similarly situated others. For example, a person might know that he is less likely to be in a car accident than similar others because he knows that he does not travel by car as often as they do. Here his optimism about this event would not be unrealistic.

A direct way to measure unrealistic optimism is to compare a research participant's actual rates of benefit/risk with respect to an event to his reported expectations of benefit/risk. For example, if we know that a particular person has a 20% chance of developing lung cancer from continued smoking and he reports that he has only a 5% chance, then his optimism about this event is unrealistic. But information about actual rates of benefit/risk as they apply to individuals is often not available, and individuals often have difficulty quantifying their expected rates of benefit/risk. In addition, discrepancies between actual and reported rates of benefit/risk may be the result of misunderstanding and not the product of a bias. For these reasons, unrealistic optimism is typically measured as a group mean response to comparative questions about specific events or hazards. Individuals complete questionnaires that ask them to compare their own chances of experiencing an event with similar others. Importantly, on this comparative approach to measuring unrealistic optimism, one can know that a group as a whole manifests unrealistic optimism with respect to an event without knowing whether any particular member of the group is making an unrealistic assessment.[12] Thus, unrealistic optimism is an event-specific bias manifested by individuals, but measured at the level of the group. However, in contexts in which there are no known factors that might make some individuals more or less susceptible to risk and/or benefit than others—such as the context presented by participation in early-phase oncology trials—an individual's claim that she is more likely to receive benefits than similar others will provide direct evidence that she is unrealistically optimistic.[13]

Past research on unrealistic optimism has revealed that it has both cognitive and affective determinants. The bias can result from a need to project a positive image or avoid anxiety,[14] or from what is referred to as the "anchoring and adjustment" heuristic.[15] In the context of clinical research, the optimistic expectations of patient-subjects might be explained by one or all of these determinants. The fact that unrealistic optimism has affective as well as cognitive determinants is relevant to appreciating its impact on the informed consent process in clinical research. Unrealistic optimism need not result from cognitive mistakes about the risks and benefits associated with an event. People with an adequate understanding of the risks and benefits can still misapply this information to themselves. This point may help to explain why unrealistic expectations of benefit among patient-subjects in early-phase oncology trials have been shown to persist even after the therapeutic misconception has been dispelled.

Our study compared assessments of unrealistic optimism with individuals' reported understanding of the purpose of the trial in which they participated. Using instruments based on those developed in earlier research on unrealistic optimism, we assessed the prevalence and magnitude of unrealistic optimism among participants of early-phase oncology trials, and whether unrealistic optimism was significantly related to therapeutic misconception. We hypothesized that unrealistic optimism would be present in this population and unrelated to therapeutic misconception.

Study Methods

We asked 88 patients to participate in the study. Eleven refused and five were too sick to participate. Written and verbal informed consent was obtained from all participants. The study was approved by the institutional review board (IRB) at New York Medical College and St. Vincent's Medical Center.

Participants were asked to complete two brief questionnaires. The first questionnaire collected demographic information. The second questionnaire was the Comparative Risk/Benefit Assessment Questionnaire, modeled on one developed by Weinstein; instruments of this type have been used in numerous studies to assess unrealistic optimism among targeted populations.[16] It asked participants to rate whether their chances of experiencing each of a series of five events were greater than, less than, or about the same as the chances of other patients participating in the same cancer research trial. The questions concerning these five events were designed to assess unrealistic optimism with respect to each event.

Participants were instructed to use the following description of other patients as a frame of reference in making their comparisons: "The average cancer patient who enrolls in an early-phase cancer research study is someone who has already tried at least one, but perhaps several, kinds of therapies and these therapies have failed to control his/her cancer." The five events concerned cancer and research-related risks and benefits (Appendix A). The Comparative Risk/Benefit Assessment Questionnaire was assessed on a seven-point scale ranging from −3 to 3 (−3 = much below average, −2 = below average, −1 = slightly below average, 0 = average, 1= slightly above average, 2= above average, and 3 = much above average). The cutoff for a response coded as unrealistic optimism was set at 1 or −1 depending on the direction of the question. This is a very common method of measuring perceived comparative risk.

After completing the questionnaires, participants were asked an open-ended question to test their understanding of the purpose of their cancer trial. This "Purpose Question" was worded as follows: "What is your understanding of the purpose of the cancer research trial in which you are going to participate?" Two of the authors (LAJ and JSF) who were unaware of how

participants had responded to the Comparative Risk/Benefit Assessment Questionnaire coded the responses to the Purpose Question. These responses were coded into one of three categories: 1) to produce generalizable knowledge that will benefit future patients (e.g., “to try to help more patients in the future deal with the same kind of cancer”); 2) to provide therapeutic benefits to the participants in the research (e.g., “so it will control my cancer”); or 3) to produce a combination of therapeutic benefits to participants and benefits to future patients (e.g., “to help others as well as to hopefully get me well”). The responses were rated separately by the coders, who achieved 93% agreement. Discrepant codings were discussed until a final consensus outcome was achieved. A one-sample t-test was conducted to determine whether there was a significant relationship between responses to the Purpose Question and the optimism scores measured by the Comparative Risk/Benefit Assessment Questionnaire responses.

Study Results

We administered a survey to 72 English-speaking patients over age 18 who were enrolled in a phase I, phase I/II, or phase II clinical cancer trial at a major comprehensive cancer center in the New York City metropolitan area between August 2008 and October 2009.[17] Background and medical information on respondents is presented in Table 1. Respondents did not differ from nonrespondents with respect to age, gender, and type of cancer.

Means and standard deviations on the Comparative Risk/Benefit Assessment Questionnaire are reported in Table 2. Unrealistic optimism was assessed using one-sample t-test comparisons against a mean rating value of zero, which represents neither optimism nor pessimism. Depending on the wording of the questions, either a positive or negative mean score indicates an optimistic bias.[18]

Significant levels of unrealistic optimism were found on three of the five cancer-related events. Respondents demonstrated the optimistic bias when asked about the possibility of their cancer being controlled by drugs administered in the trial ($p < 0.050$), experiencing health benefits from participating in the trial ($p < 0.001$), and not experiencing health problems from the drugs administered in the trial ($p < 0.050$). In other words, respondents generally believed that they would fare better than the average patient enrolled in the same trial on these dimensions, reflecting unrealistic optimism. No significant optimistic bias was found on the two events related to cancer cures.

Responses to the Purpose Question were obtained from 70 of the 72 participants. A substantial majority of respondents (72.9%) said that the purpose of the oncology trial in which they were enrolled was to advance generalizable knowledge with the potential to benefit future patients. Twenty-four percent (24.2%) reported some other purpose for the oncology trial, and a very small number reported a combination of purposes. The small number of subjects (2.9%) who reported a combination of purposes was dropped from the statistical analysis of this domain. A one-sample t-test was conducted to determine whether there was a significant relationship between responses to the Purpose Question and the optimism scores (with respect to the five cancer-related events) reported on the Comparative Risk/Benefit Assessment Questionnaire. No significant relationship existed between responses to the Purpose Question and the unrealistic optimism scores. Mean scores are reported in Table 3.

Discussion

Our hypothesis that unrealistic optimism would be present in a population of patients enrolled in early-phase oncology trials was confirmed. However, we found no significant

relationship between unrealistic optimism scores and misunderstanding about the purpose of these trials. These are important results, as it has been widely assumed that patients' expectations of therapeutic benefit from participating in early-phase oncology trials primarily either reflect a cognitive mistake—a failure to distinguish the context of research from the context of therapeutic medicine—or merely express a hopeful state of mind. Our results suggest that the reality is more complex than has been assumed. Although a minority of the respondents in our study (24.2%) did exhibit misunderstanding about the purpose of the trial in which they were enrolled, their scores related to unrealistic optimism were not significantly different from the respondents who did not exhibit this misunderstanding. The optimistic bias thus provides an independent explanation for patients' expectation of therapeutic benefit from participating in early-phase oncology trials. Importantly, many more respondents exhibited unrealistic optimism than exhibited therapeutic misconception.

Respondents in our study, as a group, did not exhibit unrealistic optimism with respect to two of the five cancer-related events. The bias was not present when they were asked about the likelihood that the trial in which they were participating would cure their cancer. They also did not manifest the bias when asked to consider the likelihood that existing drugs, available outside of the trial, would cure their cancer. Respondents may have come to terms with their cancer in the sense that they did not perceive that it could be cured. If so, then the salient feature of their participation in the trial may have been its perceived potential to control, rather than cure, their disease. Having failed standard therapy, they may have viewed the inefficacy of existing cancer treatments as settled and outside their control. This possibility would be consistent with the hypothesis that the bias emerges more for events that are perceived to be controllable (that is, perceived to be affected by behavior). Additional research on the specific cognitive and affective determinants of unrealistic optimism in this context would be needed to substantiate these conjectures.

Our study suggests that the optimism expressed by patient-subjects in early-phase oncology trials reflects something more than a disposition to think positively. As we have explained, hopeful people need not exhibit an optimistic bias. They may be dispositionally optimistic, for example. It is possible that a participant in a cancer trial might express hope that the trial will control his cancer, but not express the view that he is any more likely than similar others to benefit from the trial. Likewise, people who do not have a hopeful outlook on life may nonetheless exhibit unrealistic optimism.[19] As a bias, unrealistic optimism may or may not be accompanied by a hopeful state of mind. But since it is a bias, unrealistic optimism has the potential to compromise the informed consent of participants in clinical trials. Nonetheless, explaining how unrealistic optimism bears on informed consent is not a straightforward matter. The standard model of valid informed consent for research involves four components: 1) provision of information; 2) understanding; 3) decision-making capacity; and 4) voluntariness. Unrealistic optimism is not a function of misunderstanding. While in some settings the optimistic bias has been associated with poor comprehension and application of risk information,[20] we found no significant relationship between unrealistic optimism and understanding as measured by the Purpose Question.

It is possible, however, that unrealistic optimism—as well as other types of biases—impairs decision-making capacity by interfering with the ability to apply information realistically. Grisso and Appelbaum have advanced the idea of "Appreciation" as a competence-related concept, one that can vary independently of understanding.[21] A bias such as unrealistic optimism that interferes with the processing of information could be viewed as a factor that compromises appreciation. Another more controversial possibility is that unrealistic optimism impairs or diminishes the voluntariness of informed consent. Jansen has distinguished a strong from a weak requirement of voluntariness.[22] On the weak requirement, a voluntary decision is one that is made in the absence of external factors such

as coercion or manipulation. On the strong requirement of voluntariness, a voluntary decision is one that is not only free from coercion and manipulation, but also from a range of well-understood internal factors, such as cognitive and affective distortions, that have been shown to compromise autonomous agency.[23] The weak requirement is the one that is usually appealed to in analyses of informed consent to medical practice and research. However, outside of medicine, philosophers and lawyers have often recognized that internal factors can compromise voluntariness.[24] Whether they are characterized as exhibiting a defect regarding appreciation or voluntariness, unrealistically optimistic persons typically are not aware that they are unrealistically optimistic. The bias operates behind their back. This general fact about biases explains why unrealistic optimism might pose a threat to informed autonomous consent in medical research.

The findings from our study thus may point to the need to broaden the traditional model of informed consent, at least as it applies to clinical research. An informed decision to participate in an early-phase oncology trial is a voluntary decision made by an agent who has decision-making capacity, understanding, and appropriate information. But if a bias such as unrealistic optimism can compromise either the appreciation necessary for decision-making capacity or the voluntariness necessary for autonomous decision-making, then it is a factor that must be accounted for in the traditional model.

In emphasizing how unrealistic optimism could pose a threat to informed consent to participate in early-phase oncology research, we do not wish to rule out the possibility that unrealistic expectations for benefit in this context could also have positive effects. Some studies have suggested that unrealistic optimism is adaptive.[25] In the context of early-phase oncology trials, one study, in particular, found an inverse relationship between optimistic expectations for benefit and symptoms of depression.[26] However, a number of studies have challenged the claim that unrealistic optimism promotes mental and physical health.[27] A recent survey of the literature on the topic concludes that the "balance of studies suggest that self-enhancement biases—usually unrealistic optimism about future health outcomes—is associated with higher risk, poorer knowledge of and attention to health risk information, greater use of defense strategies when processing such information, and more risky behavioral intentions and actual behavior."[28] Accordingly, even if unrealistic expectations for benefit generally were found to have some positive health effects, there would still be reason to worry about the impact of unrealistic optimism on the informed consent process in early-phase cancer trials. More research on both the negative and positive effects of unrealistic optimism in this context is needed before a firm verdict can be reached on its ethical significance.

We acknowledge several limitations to our study. It provides only preliminary evidence for the existence of the optimistic bias among participants in early-phase oncology trials. Moreover, the generalizability of the findings is limited by the homogeneity of the sample with respect to race and diagnosis and the fact that the study was conducted at a single institution. In addition, the distribution of malignancies in the patient-subjects interviewed was skewed away from solid tumors. This was a function of the patient population at the institution at which the study was conducted. Although a growing literature suggests that unrealistic optimism can have causal effects on subsequent behavior and negative experiences, we did not establish that the bias had these effects in our study. We have not studied the population of patients who declined to participate in early-phase cancer trials and therefore do not know whether this population also exhibits unrealistic optimism with respect to cancer-related events.

In overlooking the possibility of unrealistic optimism among participants in early-phase oncology trials, researchers and ethicists have failed to engage with a substantial body of

work, both theoretical and empirical, that raises questions about optimism and its potential for compromising the informed consent of research participants. A number of writers simply have asserted that hope and optimism in the research context are always ethically benign without considering the possibility that they reflect a bias. Others have claimed that unrealistic expectations for benefit are a result of misunderstanding and that the proper response to them is to provide patient-subjects with more information about the nature and purpose of these trials. Yet if participants in early-phase oncology trials have an optimistic bias, as the present study suggests, then giving them more information will not remedy the problem. Improving the consent process in oncology research will require us to do more than address deficits in understanding. It will require us to pay more attention to how patient-subjects apply information to themselves and to become more aware of the social-psychological factors that might impair decision-making in this context.

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18. For events designated as “existing drugs,” “cancer controlled,” “health benefit,” and “cancer cured,” a positive mean score indicates an optimistic bias. For the event designated “health problem,” a negative mean score indicates an optimistic bias.
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Table 1

Background and Medical Information for Surveyed Patients Enrolled in Clinical Cancer Trials N = 72

Enrolled in phase I cancer trial	32 (45%)
Enrolled in phase I/II cancer trial	3 (4%)
Enrolled in phase II cancer trial	37 (51%)
Age range	44–84
Mean age	66.5
Female	28 (39%)
Male	44 (61%)
Ethnic composition	
White	57 (79%)
African American	5 (7%)
Black (not of U.S. origin)	4 (6%)
Hispanic	3 (4%)
Asian or Pacific Islander	2 (3%)
Other	1 (1%)
Education level	
Graduate or professional school completed	24 (33%)
College degree	19 (26%)
High school diploma	27 (38%)
Grade school	2 (3%)
Religious affiliation	
Catholic	34 (47%)
Protestant	9 (13%)
Jewish	6 (8%)
Atheist	3 (4%)
Agnostic	2 (3%)
Other	18 (25%)
Malignancies affecting respondents	
Blood cancer	41 (57%)
Myelodysplastic syndrome	29 (41%)
Breast cancer	1 (1%)
Lung cancer	1 (1%)

Table 2

Prevalence of Unrealistic Optimism with Respect to Various Events among Patients Enrolling in Early-Phase Oncology Trials

	Percent of participants demonstrating unrealistic optimism	Mean	Standard deviation	t value	p value	Cohen's d
Compared with other trial participants how likely are you to						
Have your cancer cured by standard drugs?	26.4	−0.17	1.67	−0.86	NS	−0.207
Have you cancer controlled by the drugs in the trial?	59.7	1.00	1.18	7.22	$p < 0.050$	1.714
Experience a health benefit from the drugs in the trial?	62.5	1.04	1.22	7.27	$p < 0.001$	1.726
Experience a health problem from the drugs in the trial?	38.9	−0.37	1.24	−2.57	$p < 0.050$	−0.610
Have your cancer cured by the drugs in the trial?	40.3	0.17	1.62	0.88	NS	0.210

Table 3

Relationship between the Purpose Question and Unrealistic Optimism

Unrealistic optimism questions	Generalizable knowledge N = 51	Therapeutic benefits N = 17	p value	t value	Cohen's d
Existing drugs	0.37 N = 53	0.24	NS	−1.325	−0.326
Cancer controlled	1.08	0.71	NS	1.145	0.278
Health benefit	1.00	1.12	NS	−0.348	−0.084
Health problem	0.49	0.00 N = 16	NS	−1.687	−0.409
Cancer cured	0.00	0.56	NS	−1.231	−0.301

Appendix A

Comparative Risk/Benefit Assessment Form

Cancer and research-related questions:

Compared with other patients participating in the same cancer research trial you are participating in, what are the chances:

1 your cancer will be cured with existing drugs or treatments (not those being tested in the trial) [existing drugs]

2 your cancer will be controlled by the drugs you get in the trial [cancer controlled]

3 you will experience a health benefit from participating in the trial [health benefit]

4 you will experience a health problem from the drugs being tested in the trial [health problem]

5 your cancer will be cured by the drugs you get in the trial [cancer cured]