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Mindsets, Informed Consent, and Research

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Cancer patients presented with the option to participate in early-phase cancer trials confront a very difficult choice. Standard therapeutic interventions have proven unsuccessful, but the prospect for significant therapeutic benefit from participating in these trials is very low. Yet there is some question whether the patients appreciate just how difficult the choice is. When patients who decide to participate in such trials are asked later to explain the decision, they often reveal unrealistically high expectations for therapeutic benefit from participation. This phenomenon, which is now widely documented in research ethics, has given rise to a complex and ongoing debate over the quality and validity of informed consent to these trials.¹ To make progress in this debate, bioethicists and researchers must come to a better understanding of these expectations and of why research participants so often have them.

In this paper, I present a new explanation for this phenomenon—one that casts light on some of the other explanations that have been proposed. The explanation I present draws on research in social psychology on what are called “mindsets” in that field and, in particular, on a distinction between *deliberative* and *implementation* mindsets. While my discussion is largely conjectural, it draws on a wealth of empirical research on the behavioral and self-assessment effects of mindsets in other contexts. If confirmed, the explanation that I outline here would have significant implications for how we understand the ethical significance of unrealistically high expectations for benefit in early-phase cancer trials, as well as for how investigators should respond to these expectations. Attention to mindset theory could prove to be vital for improving the informed consent process in clinical research.

Risk-Benefit Assessments and the Therapeutic Error

Before explaining the idea of a mindset and discussing some of the interesting results of mindset theory, I need to present a brief overview of the main possible causes of high expectations for therapeutic benefit in early-phase cancer trials. The overview should make it easier to appreciate how mindset theory can offer insight into the issues under discussion.

The starting point for my discussion is the observation that many patient-subjects enrolled in early-phase cancer trials appear to be making a mistake. They have, or at least appear to have, a distorted view of their own susceptibility to risks and benefits. This mistake can be called the “therapeutic error.” In all likelihood, this mistake has different causes. To date, three general causes of the therapeutic error have received considerable attention in the literature. These are the therapeutic misconception, unrealistic optimism, and therapeutic misestimation.² Each of these causes has been associated with certain cognitive or affective factors that further explain how the therapeutic error is generated. Further, while the causes may be present together, they need not be. A patient-subject could be under the sway of one without being under the sway of the other two.

Driven by the groundbreaking work of Paul Appelbaum and colleagues, early work on the therapeutic error highlighted the therapeutic misconception.³ Patient-subjects, it has been shown, often confuse the experimental context of clinical research with the therapeutic context of medicine. Believing an experimental intervention to be a form of therapy, patient-subjects often overestimate the likelihood of prospective benefit from participation in research. Subsequently, however, researchers discovered that the therapeutic misconception is not the only determinant of the therapeutic error. Even when patient-subjects are not under the therapeutic misconception, they still can have distorted risk-benefit assessments. They may be subject to a bias—unrealistic optimism—that leads them to judge that they are more likely than other people to benefit from their participation in these trials, even if their situation is similar to that of the people they compare their prospects to. Alternatively, they may be engaged in therapeutic misestimation: that is, they may simply have a poor understanding of the probability estimates of risks and benefits presented by the trials in which they are enrolled. These alternate causes of the therapeutic error are more tightly related to risk-benefit assessments than the therapeutic misconception, as they bear more directly on them. In fact, a person could be under the therapeutic misconception while having a fully accurate understanding and appreciation of the risk-benefit profile of the trial in which she participates.⁴

Significant progress has been made in understanding how each of these causes of the therapeutic error bear on the risk-benefit assessments of those who participate in early-phase cancer research. No research has been done, however, on the relationship between these causes of the therapeutic error and the cognitive orientations, or mindsets, of the trial participants at the time when they are surveyed. Speaking very generally, we can distinguish a predecisional cognitive orientation in which a trial participant has not yet formed the intention to participate in a research trial from a postdecisional cognitive orientation in which the trial participant has done so.⁵ For the most part, research on the therapeutic error over the past twenty-five years has been conducted on those who have already agreed to participate in cancer trials. The most influential studies on the therapeutic misconception, unrealistic optimism, and therapeutic misestimation have interviewed patient-subjects after they have consented to participate in a clinical trial.⁶ This means that the bulk of the research on the therapeutic error has been done on people who are no longer in the predecisional phase in which they are deliberating over the pros and cons of trial participation. Rather, they are in the midst of an adopted goal or plan of action. Reflection on this fact brings into view some important and interesting possibilities that deserve consideration. To see why, we must turn our attention to mindset theory.

Mindset Theory

Human beings are planning agents. We deliberate about what plans to pursue. We set goals, take up projects, and assume responsibilities. Having adopted plans, we strive to realize them, adjusting our actions in light of the plans we have made. We also make efforts to ensure that our different plans mesh and that smaller subplans are modified in light of more comprehensive plans that include them.⁷ This basic picture of human beings as planning agents provides the backdrop for mindset theory. Planned action involves different stages or action phases, and these different phases are associated with different cognitive

orientations.⁸ In simple terms, mindsets are cognitive orientations that help us to solve certain tasks.

Research on mindsets was initially conducted by the psychologist Peter Gollwitzer in the late 1980s and early 1990s.⁹ He sought to understand the successful pursuit of goals and plans. Toward this end, he observed that successful planning agency involves four action phases: a choice must be made between potential goals, decisions must be made about how to implement a chosen goal, actions must be taken to realize a chosen goal, and an assessment must be made about what has been achieved. Each action phase presents its own challenges and demands. Gollwitzer then proposed that different cognitive orientations address these different demands.¹⁰ Of greatest importance, he found, are the different cognitive orientations involved in the selection of a potential goal and those involved in its implementation. The former he referred to as the “deliberative mindset,” and the latter as the “implementation mindset.”

One of the striking results that Gollwitzer and others have discovered is that these two mindsets are associated with different assessments of one's ability to succeed in the pursuit of one's plans. As Gollwitzer observed,

People who ponder a goal decision (i.e., to either pursue Goal A or B, or to pursue either Goal A or stay passive) develop a deliberative mindset that allows them to accurately assess whether a desired outcome can be controlled by their actions or not, whereas people who are planning the pursuit of a chosen goal develop a mindset that fosters illusory optimism with respect to controlling this outcome.¹¹

In other words, when a person is asked to consider her likelihood to succeed at a future task, she will tend to make more accurate predictions if she is in a deliberative mindset than if she is in an implementation mindset. Once a person has committed to doing something, she will tend to exaggerate her ability to succeed at it. For example, while someone is considering whether to try writing a novel, she will be much less likely to be overly optimistic about her prospects for success in completing the project than she will be once she has resolved to actually do it.

The fact that an implementation mindset can affect the assessments of our goals in this way has been shown to have positive effects. As scholars on mindsets have explained, the “mere act of making a decision (which passes an individual from a predecisional to a postdecisional state) leads to increases in intrinsic motivation and enhanced performance.”¹² It might be wondered exactly how “illusory optimism” and unrealistic self-assessments could have beneficial effects for planning agents. Would it not be better for such agents always to make accurate assessments? Interestingly, the answer is no. Having settled on a goal or plan, an agent needs to focus on how to achieve it rather than be distracted by thoughts about its value or desirability. Similarly, having decided that she is able to pursue a goal successfully, an agent should not continually direct her attention to questions or information that bears on how likely she is to be successful. She will be more successful if she simply goes about doing her best to implement the goal she has adopted. Moreover, if an agent is confident, even unrealistically confident, in her abilities to succeed in the goal, then

she may be more committed to it than she otherwise would, thereby increasing her chances for success.

Numerous studies have confirmed these claims.¹³ The studies show that when people overrate the value of a goal and their ability to succeed at it, they are more likely to persist in its pursuit, especially when they encounter difficulties or obstacles. In a typical study, participants are asked to perform a task, such as play a computer game, with a promise of a reward if they perform well. Prior to playing the game, participants are randomly divided into two groups: those who have been led to have a deliberative mindset and those who have been led to have an implementation mindset. The latter group not only reports higher expectations for success than the former group but also persists longer in playing the game.

The positive effects of the implementation mindset must be balanced against its potential negative effects, however. As mentioned above, the implementation mindset has been shown to foster illusions of control. People in this mindset often believe falsely that they can control an outcome that is in reality uncontrollable, and they may therefore devote considerable time and resources to achieving unattainable goals. In a random game of chance, a person who is committed to winning the game may come to think that she can control the outcome of the game.¹⁴ She then may persist in playing the game even while losing at it, wasting time and resources to her detriment.

Illusory perceptions of control have been shown to be strongly related to unrealistic assessments of expected benefits and potential costs of plan-directed action.¹⁵ Mindset theory thus reveals an interesting way by which one's cognitive orientation mediates risk perception. Research has shown that there is a significant difference between those in the deliberative and implementation mindsets when it comes to one's perceived susceptibility to risks and benefits. For example, in several studies involving college students, participants were asked to consider a range of events, such as being in an automobile accident, developing a drinking problem, losing a partner to early death, or getting mugged. Students who had been primed to be in the implementation mindset exhibited more pronounced illusions of invulnerability than did those who had been primed to be in the deliberative mindset.¹⁶ Deliberation and the cognitive orientation associated with it appear to dampen perceptions of personal invulnerability.

Further, even if people can exercise control over an outcome, and even if they accurately assess their susceptibility to risk in pursuing the outcome, mindset theory predicts that those in an implementation mindset will tend to exaggerate or overstate the value or desirability of the adopted goal. Hence, in terms of both the perceived desirability and perceived feasibility of an adopted plan as well as the perception of risks involved in its pursuit, people in an implementation mindset will tend to be excessively optimistic. This can lead them to persist in pursuing goals longer than they should. Increased goal persistence is not beneficial when it leads individuals to "persist with failing courses of action."¹⁷

None of these claims imply that a person becomes incapable of deliberation once she has adopted a plan or goal. Mindsets are cognitive orientations, but they do not take over the mental life of planning agents. In reality, the relationship between deliberative and

implementation mindsets is complex. Action phases can overlap, and people who are implementing one goal can be called upon to deliberate about another.¹⁸ In addition, there is the commonplace fact that people can and do change their minds. New information may reveal to them either that their goals are less desirable than they had previously thought or that they are less able to pursue these goals effectively. Even so, mindset theory helps us to appreciate two important obstacles to reconsideration of adopted goals. First, reconsideration of an adopted goal is costly in terms of time and mental resources, and too much reconsideration will undermine the positive benefits associated with the implementation mindset. A good planning agent does not constantly reassess the plans she adopted in a more deliberative state of mind.¹⁹ Secondly, and possibly more importantly, mindset theory has shown that our receptivity to new information and our processing of both old and new information is affected by the cognitive orientation that we are in. Mindsets tune thought production, affecting both information retrieval and information processing.²⁰ More specifically, studies have shown that those in an implementation mindset exhibit “cognitive tuning” that is biased toward information relevant to goal pursuit and biased against information concerning its desirability and feasibility. This “comparative closed-minded focus” contrasts with those in a deliberative mindset, who exhibit “an open minded, relatively even-handed, and accurate appraisal of evidence.”²¹ The upshot is that once people are in the implementation mindset, as contrasted with the deliberative mindset, they are both more likely to have unrealistically rosy views about the goals they have adopted and less likely to reconsider their commitment to goals, even when there is good reason for them to do so.

Mindsets and Therapeutic Expectations

The central contention of this paper is that the insights of mindset theory can illuminate the process of informed consent in clinical research. Like other forms of temporally extended plan-directed action, the decision to participate in a research trial consists of different action phases. There is a predecisional action phase in which potential participants must decide whether or not to participate in a trial, and there is a postdecisional action phase in which they must take the steps required to achieve the goals of such participation. If mindset theory is correct, then these two decisional phases will tend to be accompanied by different cognitive orientations. The predecisional phase will trigger a deliberative mindset, while the postdecisional phase will trigger an implementation mindset. This raises an important and unstudied question about the nature of the therapeutic error and how it arises in early-phase oncology research. When patient-subjects are asked about their expectations for benefit from participation in an experimental research trial, what decisional phase are they in, and what cognitive orientation structures their thinking?

No one to date has addressed this question directly. As mentioned above, research on the causes of the therapeutic error has focused almost exclusively on those who are in a post-deliberation phase, having already resolved and consented to participate in an early-phase cancer trial. This fact suggests two possibilities. First, the high expectations for therapeutic benefit widely reported by participants in early-phase cancer trials may be a product of the implementation mindset. And second, those who now report high expectations for benefit and who are in the implementation mindset may have had more balanced and accurate risk-

benefit expectations when they were deliberating over whether to participate in the trials. The therapeutic error may be present when patient-subjects are in the implementation mindset but not, or not to the same degree, when they are in the deliberative mindset.

These possibilities would need to be confirmed by empirical investigation. But our discussion of mindset theory reveals why they are likely more than mere theoretical possibilities. As discussed above, the implementation mindset is linked to illusions of control and biased cognitive processing that discounts information relevant to goal assessment and feasibility. There is ample reason to think that both of these factors—illusions of control and biased cognitive processing—can help to explain the high expectations for therapeutic benefit from participation in early -phase cancer trials.

Consider first the phenomenon of unrealistic optimism. As explained above, researchers have pointed to unrealistic optimism as one potential cause for the therapeutic error. In one study, my colleagues and I found that patient-subjects demonstrated unrealistic optimism when asked about the possibility of their cancer being controlled by drugs administered in the trial and about experiencing health benefits from participating in the trial.²² (Patient-subjects also exhibited an optimistic bias when asked about the prospect of experiencing health problems from the drugs administered in the trial.) But as this study also reported, unrealistic optimism is evoked by certain risk-perception attributes. One such attribute—in particular, “perceived controllability”—was found to be strongly correlated with unrealistic optimism in this population.²³ This finding is consistent with the hypothesis that the implementation mindset stands behind, or at least contributes to, unrealistic optimism in this context. Perceived controllability with respect to an event that lies outside of one's control, such as experiencing health benefits or having cancer controlled as a result of trial participation, is an instance of the illusion of control characteristically engendered by the implementation mindset. Thus there is some evidence to support the claim that the implementation mindset generates the unrealistic optimism found in this study.²⁴

Consider next the problem of therapeutic misestimation. This, too, has been considered an important potential cause of the therapeutic error. As Sam Horng and Christine Grady have explained, the therapeutic misestimation involves a form of misunderstanding in which research participants overrate the prospective benefits or underestimate the risks of trial participation. But what accounts for this misunderstanding? The possibility suggested by Horng and Grady is that “research participants may interpret probability data differently and that participants may be predisposed to interpret probability data in their own favor.”²⁵ Research participants, they suggest, “may be inclined to interpret [probability] estimates to reflect a more optimistic outlook.” This explanation, too, is consistent with what mindset theory predicts. The implementation mindset is associated with cognitive tuning that accentuates favorable information and discounts unfavorable information. This cognitive tuning also affects the inferences people draw from the data available to them. This, in turn, can lead to distortions in probability estimates of valued outcomes. Summarizing the results of a number of experiments, Gollwitzer reports that subjects in the deliberative mindset “make rather accurate estimates of action-outcome possibilities,” which “is definitely not true of implemental mind-set subjects. They overestimate these probabilities, thus showing illusionary optimism.”²⁶

Like the illusory optimism that evokes unrealistic optimism, the illusory optimism that results from distorted probability estimates may be a product of the implementation mindset. If so, mindset theory would provide a good explanation for both unrealistic optimism about clinical trials and misestimation of their therapeutic benefit.

The therapeutic misconception remains to be discussed. Could mindset theory, in addition to explaining the other two causes of the therapeutic error, help to explain it?

Recall that the therapeutic misconception involves a confusion over the purpose of clinical research: trial participants believe erroneously that the trial is designed to benefit them rather than to produce generalizable scientific data. This mistake may also lead them to think that they will receive individualized treatment in the trial. As noted, the relationship between the therapeutic misconception and the therapeutic error is not as tight as it is under the other two causes of the therapeutic error. Trial participants could fail to understand the purpose of the trial in which they are enrolled while still making accurate judgments about the risks and benefits it presents to them and vice versa. This suggests that the therapeutic misconception may result from factors that are independent of those associated with the implementation mindset.

Nevertheless, it is worth keeping in mind that there is a distinction between the purpose of a research trial and the motives of those who participate in it.²⁷ While deliberating over the merits of participating in a trial, some patient-subjects may decide to enroll in a trial for therapeutic purposes. They might consider participation in the trial to be their best treatment plan even while fully understanding that the purpose of the trial is not to provide them with therapy, but to advance medical knowledge. Once committed to trial participation, these patient-subjects may then discount the incongruous fact that the trial is not designed to benefit them or that they will not receive individualized treatment. They may come to view the study drug as medication that has been personally selected for them for therapeutic purposes. In lengthy clinical trials, “where traditional care and research protocols have overlapping methods and personnel,” this kind of mistake would be understandable.²⁸ Mindset theory, as we have seen, predicts that cognitive orientations tune cognitive functioning, making congruous information more accessible and incongruous information less accessible to planning agents. So it is not out of the question that the implementation mindset contributes to, or plays a role in explaining, the therapeutic misconception of those who are surveyed during trial participation. This possibility is at least worth investigation.

Mindsets and Informed Consent

I have been arguing that mindset theory might help explain the therapeutic error by shedding light on the mechanisms that generate it. If this explanation turns out to be correct, it would have important implications for how we should think about the impact of the therapeutic error on informed consent and how we might go about responding to it.

The first and boldest point to make is that if the implementation mindset generates the distortions in risk-benefit assessments associated with the therapeutic error, then these distortions may not be present, or present to the same degree, at the moment when trial participants decide to enroll in the trial. This is the moment when it is most important for

them to make accurate judgments about the potential benefits and costs of trial participation. Informed deliberative consent to enroll in a trial, after all, is what we care most about. Thus mindset theory may reveal that the therapeutic error is less troublesome for informed consent than has been widely assumed. This would be a striking finding.

This bold conjecture should be treated with some caution, however. We do not really know the extent to which patient-subjects enrolled in early-phase cancer trials ever made deliberative decisions. Some of these patient-subjects may have been predisposed to join the trials prior to any informed consent discussion, and others may have perceived their participation in these trials as simply the natural continuation of their treatment plan. In these cases, the initial decision to enroll would not likely have been made in the deliberative mindset. In addition, as I have emphasized, participation in research takes place over an extended period, starting with deliberation over a plan of action and continuing through a number of distinct action phases. Likewise, consent to research is not a one-time event but a process that extends across time.²⁹ Even if trial participants gave informed deliberative consent at the moment they enrolled in a trial, they still could be subject to distortions down the road, and we should want to ensure that their ongoing consent is of high quality.

There are a couple of reasons that this is especially true for cancer patients enrolled in early-phase trials. First, it is widely assumed that these trial participants have a right to withdraw from their trial at any time without penalty. To exercise this right in an informed way, they need to be able to reconsider accurately the potential benefits and costs of continued trial participation. The therapeutic error, even if it manifested only in subjects who had an implementation mindset, would present a problem for this dimension of the informed consent process. Second, during the course of the trial, new information may become available that is relevant to the risk-benefit profile that the trial presents to its participants. For example, information may be discovered that concerns the risks or side effects of the drugs in the study or concerns facts about the clinical condition of a trial participant. Informed consent to continue participating in a trial requires that new information of this kind be incorporated into the assessment by the patient-subject of the risks and benefits of continued participation. If she is in the implementation mindset, however, then mindset theory predicts that she will be cognitively disposed to discount or downplay this new information, as it bears on the expected value of her plan as opposed to how the plan might be best carried out.

The diachronic nature of informed consent in research thus gives us plenty of reason to care about the therapeutic error, even if we come to believe that the error is largely the product of the implementation mindset and does not imply that the initial deliberative consent to participate in the research was distorted. A less dramatic but more probable possibility is also worth serious consideration. The implementation mindset may simply reinforce or magnify the therapeutic error. The error may be present when patient-subjects are deliberating whether to enroll in an early-phase cancer trial, but it could be enhanced once they have decided to enroll in the trial. This possibility would also be important to confirm, since it would suggest novel strategies for counteracting the therapeutic error among patient-subjects participating in trials of this kind. The strategies would focus on fostering the cognitive orientation associated with deliberation. If mindset theory is correct, then the

deliberative mindset should dampen the illusions of control and the cognitive closedmindedness associated with the implementation mindset, which in turn should counteract the hypothesized reinforcement or magnification of the therapeutic error.

In effect, mindset theory suggests a new model for informed consent. The model can be called the *diachronic deliberative model*. It emphasizes the fact that consent to participate in research is an ongoing affair, not a one-time event, and in this respect, it builds on the process model for informed consent that has been proposed by others.³⁰ But the diachronic deliberative model goes beyond the process model by incorporating the insights of mindset theory into its account of the deliberation needed for high-quality informed consent. The model likely has broad application. Efforts to improve consent to therapeutic interventions, as well as consent to participate in experimental research trials, would likely benefit from attention to mindset theory.

Applied to early-phase cancer trials, the diachronic deliberative model imposes new responsibilities on physician-investigators. It suggests that investigators have a responsibility not only to seek ongoing consent from trial participants but also to take steps to ensure that trial participants are in the appropriate mindset when ongoing consent is elicited. The process model of informed consent recommends an ongoing negotiation between physician and patient over the goals of their care and thus suggests that patients should be encouraged to engage in deliberation throughout the plan of treatment. But mindset theory calls attention not only to the benefits of the deliberative mindset but also to those of the implementation mindset. Too much deliberation can be debilitating, and it can obstruct the efforts of planning agents to achieve goals. The implementation mindset facilitates the successful pursuit of goals and plans. For this reason, consent to participate in an experimental cancer trial should be ongoing but need not be continuously deliberative. Instead, physician-investigators should encourage patient-subjects to be in the deliberative mindset in contexts that call for deliberation—that is, when patient-subjects have reason to reexamine the desirability of their continued participation in the trial. When new information relevant to the risk-benefit assessment of continued trial participation is discovered, for example, investigators would need to make efforts to counteract the effects of the implementation mindset when disclosing this information to trial participants.

The diachronic deliberative model assumes that investigators can discharge these responsibilities successfully and that discharging them is not unreasonably demanding. Are these plausible assumptions? Research on mindsets points tentatively to an affirmative answer. In their research, Gollwitzer and colleagues discovered several interesting facts about mindsets.³¹ First, the deliberative mindset can be induced relatively easily by asking a person to think about the pros and cons of an important personal decision, such as the decision to change jobs or buy a new car. Second, mindsets tend to generalize across situations. If one is induced into the deliberative mindset by thinking about a personal problem, then one will continue to be in that mindset when one turns one's attention to other, unrelated tasks or problems. And, third, mindsets show some stability over time.

These general facts about mindsets suggest a method for inducing subjects into the deliberative mindset for purposes of securing informed consent to clinical research. The

method would invite trial participants to consider an important personal problem, weighing the pros and cons of alternative decisions. Having encouraged the deliberative mindset in this way, investigators could then initiate the consent procedure, inviting trial participants to consider the question of whether they wished to continue participating in the trial in light of any new information, either about the drugs in the trial or their own situation, that had emerged since their last explicit consent. The method indirectly primes the deliberative mindset. The same effect might be achieved by directly encouraging trial participants to think about the pros and cons of their initial decision to enroll in the trial. This more direct approach, however, could do worse by provoking ego defensiveness.³² If trial participants engage in defensive deliberation, they will discount negative information and accentuate positive information. Whether direct or indirect priming of the deliberative mindset is more conducive to unbiased deliberation is an issue that would need to be studied.

I have presented only a bare sketch of how the method might function in practice. But the key idea behind the method is more important than its details, which could be worked out if implementation mindsets were indeed found to be a significant cause of the high expectations for therapeutic benefit by patient-subjects in early-phase cancer trials. Even if mindset theory proved to be less robust in explaining the therapeutic error than I have proposed, it could still make a significant contribution to ongoing efforts to improve the informed consent process in both medicine and research.

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