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Risk perception and risk attitude in informed consent

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Abstract

The standard account of the 'reflection effect' (Kahneman and Tversky, 1979) is that attitude toward risk changes across gain or loss framings of outcomes. Weber and Bottom (1989) proposed an alternative account in which decision makers have stable risk attitudes, but changing risk perceptions. Undergraduates were randomly assigned to read one of three hypothetical informed consent documents from a trial of a cholesterol-lowering drug. Documents used gain, loss or both framings to describe expected benefits. Respondents rated riskiness of participation and non-participation in the trial and made a choice about whether they would participate in the trial.

The reflection effect was replicated. In addition, as predicted by the Weber and Bottom account, respondents in the gain condition were more likely to rate participation as riskier than non-participation compared to respondents in the loss condition, and in each condition more than 70 per cent of respondents chose to avoid the option they judged as riskier. Implications for informed consent are discussed.

1. Introduction

Kahneman and Tversky (1979) showed that risk preferences often reflect around the status quo: people are risk averse in the domain of gains and risk seeking in the domain of losses. This reversal of risk preferences is referred to as the reflection effect, and has been demonstrated with money, time, human life, and a variety of other outcomes in both between-subjects and within-subjects designs.

The standard account of the reflection effect was also proposed by Kahneman and Tversky by prospect theory. Prospect theory posits a value function on changes in outcomes from the status quo; the function is steeper for losses than gains. It also defines a probability-weighting function that implies that small probabilities are overweighted, large probabilities are underweighted, and certainty is overweighted. Together, these functions with their most typical parameters imply that in choices between sure outcomes and gambles involving probabilities that are not very small, risk preferences will reflect around the status quo. That is, preference for a high- vs.

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a low-variance or certain alternative is based on the decision maker's (domain-varying) attitude toward outcome variance. 'Risk' implicitly refers to outcome variance in this formulation.

Recent work by Weber and colleagues (Weber and Bottom, 1989; Weber and Milliman, 1997; Mellers, Schwartz, and Weber, 1998) offers an alternative account, based on the perception of risk by the decision maker. Under this account, decision makers may have stable perceived-risk attitudes (e.g. perceived-risk aversion) across domains, but may perceive the riskiness of alternatives differently when the alternatives are framed as gains and losses. That is, preference for a high- vs. a low-variance alternative is based on which alternative is perceived by the decision maker to be riskier and the decision maker's (domain-invariant) attitude toward perceived risk.

For this account to provide an adequate explanation of the reflection effect, people who are risk-averse must perceive high-variance gambles as riskier than low-variance gambles when framed as gains, but low-variance gambles as riskier than high-variance gambles when framed as losses. Weber and Bottom (1989) found exactly this pattern of perceptions for most of their respondents in choices between pairs of lotteries, as did Mellers, Schwartz, and Weber (1997). For example, in the latter study, subjects who were perceived-risk averse judged a gamble with an 80 per cent chance of losing $44 and a 20 per cent chance of losing $24 to be riskier than a gamble with an 80 per cent chance of losing $48 and a 20 per cent chance of losing $10 when asked to directly compare them and choose the riskier gamble. Weber and Milliman (1997) replicated the result for choices between commuter trains with risky arrival times and for MBA students' choices between stocks in an investment game. Clearly outcome variance is not the same as subjective perception of riskiness.

The accounts are not mutually exclusive. Both of these accounts predict the reflection behavior; they differ in the underlying motivation, particularly in the domain of losses. The standard account, which defines risk as outcome variance, holds that higher variance alternatives are riskier and that higher variance alternatives are preferred, resulting in behavior that is both variance-seeking and risk-seeking. The perceived-risk account holds that lower variance alternatives are in fact perceived as riskier, and riskier alternatives are avoided, resulting in behavior that, while variance-seeking, is (perceived-) risk averse. Key advantages of the pereeived-risk account are that it provides the opportunity to rescue (perceived-) risk attitude as a stable trait across situations by unconfounding risk preference from risk perception (Weber, 1997), and that it directs attention to the importance of addressing risk perception when seeking to change choices. For example, in a study with respondents from China, the United States, Germany, and Poland, Weber and Hsee (1998) found that cultural differences in risk attitude were primarily differences in risk perception combined with relatively stable risk preferences. They suggest that it might be possible to reframe cross-cultural negotiations to achieve joint gains by taking advantage of differences in the parties' risk perceptions.

Past research has focused primarily on gambles involving money or time. Although risk perception and risk attitude are important topics of study in health psychology, less work has integrated these recent findings with an eye to health applications. Notably, people make risky decisions about their health when they consider enrolling in a clinical trial. With respect to the reflection effect itself, findings have been

decidedly mixed in health decisions. Both McNeil *et al.* (1986) and O'Connor (1989) found some evidence for *increased* risk aversion when outcomes of decisions about cancer therapies were framed in terms of losses. Llewellyn-Thomas, McGreal, and Thiel (1995) and Zimmermann, Baldo, and Molino (2000) did not find framing effects in cancer patients making similar decisions about participation in a chemotherapy trial.

Informed consent in clinical trials has become a subject of considerable importance, as increasing numbers of trials have become available, and as regulatory bodies have required greater explicitness about potential risks and benefits of trial participation. These changes have caused some to inquire about whether patients are suitably informed about their participation, and exploration of the impact of informed consent documents (Hux and Naylor, 1995).

When the decision may be substantially impacted by the way in which outcomes are framed, understanding risk perception and risk attitudes becomes crucial in avoiding ethical dilemmas in shared medical decision making and in designing educational materials for risk communication. To determine whether the reflection effect and perceived-risk account could be replicated in a medical context, we conducted a single-trial between-subject experiment of the effects of gain/loss framing on risk perception and attitude in the context of (hypothetical) informed consent to a clinical trial.

2. Materials and methods

Undergraduate respondents were recruited in a student union at the campus of an urban research university. They were randomly assigned to one of three groups: 'gain', 'loss', or 'both'. In each group, respondents were asked to imagine that they had hypercholesteremia (high blood cholesterol levels) and read information about hypercholesteremia and a hypothetical informed consent document for a clinical trial of a new cholesterol-lowering drug. High cholesterol was chosen because it is a chronic and typically asymptomatic medical condition with which college students are likely to be familiar, even if they have not experienced it themselves. The trial information was written so that the outcomes of participation (serious allergy, improvement, or no change, with explicit uncertainty) would be perceived as higher variance than the outcomes of non-participation (the default alternative treatment, with no explicit uncertainty):

> Hypercholesteremia, or high cholesterol, is a major factor in heart disease, the single largest cause of death in the United States. More people die from heart disease than from all types of cancer, diabetes, AIDS, and accidents combined. Although many people can lower their cholesterol to healthy levels by changing their diet or exercise habits, some people require drugs to lower their cholesterol level.
>
> Imagine that you have high cholesterol that diet and exercise changes haven't helped to lower, and that you are allergic to the most commonly prescribed anti-cholesterol drug. After meeting with your doctor to discuss your options, your doctor tells you about a clinical trial of a new drug, Fixitimine, that has been suggested for lowering cholesterol. Here is the informed consent agreement for the clinical trial:
>
> Consent to Participate in a Research Study: Cholesterol-lowering Effects of Fixitimine

Purpose of the study
The study involves the administration of Fixitimine, an investigational anti-cholesterol drug, once daily by mouth for twelve weeks. I understand that the purpose of this study is to see if the investigational drug Fixitimine is safe and effective when used to treat high cholesterol.

Procedure
The study will last 12 weeks. During that time, I will take one Fixitimine tablet each day by mouth. I will receive a complete physical examination before and after the study, which will include laboratory blood tests. The amount of blood that will be drawn from a vein in my arm will be about two tablespoonsful. At all visits, my blood pressure and heart rate will also be monitored.

Possible Benefits and Risks
By participating in this study, I may help identify a possible alternative medication in the treatment of high cholesterol. If Fixitimine proves to be both safe and effective for my condition, I may continue taking it as part of an extended study until the drug is approved.

Anyone taking this drug has a small risk of a severe allergy that could result in death. Out of 100 people whose lives would likely be cut short by heart disease and begin taking this drug, we expect that 95 will show substantial improvements in their chance of survival and 5 will show no improvement in survival.

Alternatives to Participation
If I do not participate in this study, my doctor will suggest an appropriate existing drug or non-drug therapy to treat my high cholesterol.

Monetary Compensation/Treatment Costs
I understand that I will not have to pay for the cost of the medication that I will receive during this study, or for the physical exams and labwork associated with this study.

Compensation for Injury
In the event of physical injury or illness related to this research, immediate medical treatment will be made available. However, there is no compensation and/or payment for such treatment except as may be required by law.

Confidentiality
My medical records will be held in the strictest confidence by all individuals involved in this study. I understand that agents of the U.S. Food and Drug Administration (FDA) and of NewDrugs, Inc. may have access to pertinent sections of my medical records, but will maintain confidentiality of those records. Reports or publications resulting from this study will not identify me by name.

Right of Refusal
I understand that participation in this study is voluntary and that refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I understand that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand that the investigator has the right to withdraw me from the study at any time. All of my questions about this study have

been answered and I freely and voluntarily consent to participate. I may keep a copy of this consent form.

Information in each group's consent document was identical except for the second paragraph describing the probable risks and benefits of the new drug. In the gain group, benefits were framed in terms of gains. For example:

> Anyone taking this drug has a small risk of a severe allergy that could result in death. Out of 100 people whose lives would likely be cut short by heart disease and begin taking this drug, we expect that 95 will show substantial improvements in their chance of survival and 5 will show no improvement in survival.

In the loss group, benefits were framed in terms of losses:

> Anyone taking this drug has a small risk of a severe allergy that could result in death. Out of 100 people whose lives would likely be cut short by heart disease and begin taking this drug, we expect that 5 people will go on to die from heart disease, and 95 people will reduce their chance of death.

In the both group, both framings were presented in the paragraph:

> Anyone taking this drug has a small risk of a severe allergy that could result in death. Out of 100 people whose lives would likely be cut short by heart disease and begin taking this drug, we expect that 5 people will show no improvement and will go on to die from heart disease, and 95 people will substantially improve their chance of survival and reduce their chance of death.

Respondents were asked to rate the riskiness of participation in the clinical trial and the riskiness of non-participation in the clinical trial on a category rating scale ranging from 1 ('not at all risky') to 10 ('extremely risky'). Finally, respondents indicated whether they would participate in the trial or not. Respondents were paid $4 each for participation in the study.

A sample size of 97 respondents per group (291 respondents total) was determined by power analysis to be sufficient to detect the difference between a 70 per cent participation rate in the loss framing and a 30 per cent participation rate in the gain framing with 80 per cent power using a chi-square test with a 0.05 significance level. This sample size offers 92 per cent power to detect a difference of 1 standard deviation in the ratings of riskiness between pairs of groups.

As the premise of the research question is that respondents will exhibit reflection behavior and that this behavior can be well-explained by changing risk perceptions but consistent perceived-risk attitudes across domains, the following hypotheses were tested with these data:

> H1 (reflection effect): A significant majority of respondents will choose to participate in the clinical trial when outcomes are framed as losses; a significant majority will choose not to participate when outcomes are framed as gains.
> H2 (framing and perceived risk): When outcomes are framed as gains, participation in the trial will be judged as relatively *riskier* than non-participation; when outcomes are framed as losses, participation will be judged as relatively *less risky* than non-participation.
> H3 (perceived-risk aversion): In each domain, respondents will make the choice associated with the lesser perceived risk.

H1 is the expected reflection effect in choice behavior; H2 describes the pattern of risk judgments that would be necessary to support a perceived-risk account of the reflection effect; H3 specifies the behavior predicted by the perceived-risk account.

3. Results

A total of 284 undergraduates at the University of Illinois at Chicago participated in the study. One respondent did not complete one of the risk ratings and is excluded from the analyses that follow. Of the remaining respondents, 92 were assigned to the gain condition, 98 to the loss condition, and 93 to the both framings condition.

DID CHOICES REFLECT ACROSS FRAMINGS?

As hypothesized, a majority of respondents chose to participate when outcomes were framed as losses (59 per cent), and a majority of respondents chose not to participate when outcomes were framed as gains (65 per cent); these proportions differed significantly from 50 per cent in the predicted directions by one-tailed binomial tests. Respondents who saw outcomes framed as both gains and losses made choices that resembled respondents in the loss condition: 62 per cent chose to participate in the trial. The results support the presence of the reflection effect in choice behavior in our respondents.

DID PERCEIVED RISK REFLECT ACROSS FRAMINGS?

Table 1 displays the mean riskiness ratings for participation and non-participation for respondents in each of the three conditions. Respondents in the gain condition rated participation as riskier than respondents in the loss condition (6.2 vs. 5.6, $t(188) = 1.813$, $p < 0.05$, one-tailed), and respondents in the loss condition rated non-participation as riskier than respondents in the gain condition (5.1 vs. 4.0, $t(188) = 3.283$, $p < 0.05$, one-tailed). Ratings of riskiness of participation and riskiness of non-participation in each of the groups are moderately but significantly negatively correlated. Accordingly, it is more appropriate to consider only a test of relative risk of participation vs. non-participation.

Table 2 tabulates the number of respondents who rated participation as more risky, equally risky, or less risky than non-participation in each domain. In the domain of gains, 66 per cent of respondents rated participation as riskier, 22 per cent rated non-participation as riskier, and 12 per cent rated participation and non-participation as

Table 1. Ratings of riskiness of participation and non-participation in each condition.

	Condition		
	Gain	*Loss*	*Both*
Risk of participation	6.18 (2.08)	5.63 (2.11)	5.55 (2.29)
Risk of non-participation	3.98 (2.14)	5.07 (2.42)	4.44 (2.33)
N	92	98	93

Note: Values are mean ratings, with standard deviations in parentheses. Riskiness was rated on a scale from 1–10.

Table 2. Respondents classified by comparison of risk of participation and non-participation.

	Condition		
	Gain	*Loss*	*Both*
Participation riskier than non-participation	61 (66%)	54 (55%)	48 (52%)
Participation and non-participation equally risky	11 (12%)	5 (5%)	12 (13%)
Participation less risky than non-participation	20 (22%)	39 (40%)	33 (35%)

Note: Values are numbers of respondents in each classification. Percentages within each domain appear in parentheses.

equally risky. In the domain of losses, 55 per cent rated participation as riskier, 40 per cent rated non-participation as riskier, and 5 per cent rated participation and non-participation as equally risky. There was a significant association between domain (gain vs. loss) and relative riskiness of participation vs. non-participation ($\chi^2(2) = 8.6,\ p < 0.05$). As hypothesized, respondents in the gain condition were more likely to rate participation as relatively riskier than non-participation compared to respondents in the loss condition. When both gain and loss framings were presented, the results again were more similar to the loss condition: 52 per cent of respondents rated participation as riskier than non-participation, 35 per cent rated non-participation as riskier, and 13 per cent rated participation and non-participation as equally risky.

WHAT ARE RESPONDENTS' PERCEIVED-RISK ATTITUDES?

Respondents were classified as perceived-risk seeking (PRS) when they either (a) rated participation in the clinical trial as riskier than non-participation and chose to participate, or (b) rated non-participation as riskier than participation and choose not to participate. Respondents were classified as perceived-risk averse (PRA) when they either (a) rated participation as riskier than non-participation and chose *not* to participate, or (b) rated non-participation as riskier than participation and chose to participate.

Table 3 shows, for each domain, a cross-tabulation of respondents by their (classical variance-based) risk attitudes and their perceived-risk attitudes. As hypothesized, most respondents were perceived-risk averse in each domain. In the domain of gains, 58 of 81 respondents (71.6 per cent) were PRA. In losses, 69 of 93 respondents (74.2 per cent) were PRA. When both gain and loss framings were presented, 57 of 81 respondents (70.4 per cent) were PRA. It is notable that these proportions are very similar; in contrast to the pronounced reflection effect that appears when risk attitudes are based on preference for high- or low-variance alternatives, perceived-risk attitudes are remarkably stable across domains.

Twenty-eight respondents who rated participation and non-participation as equally risky were excluded from the above analysis (12 in the gain condition, 5 in the loss condition, and 11 in the both condition). In the gain condition, 6 of these 12 respondents chose to participate, and 6 chose not to participate. In the loss condition, all 5 of these respondents chose to participate in the trial, which is mildly suggestive of a preference for higher variance in losses even when perceived risk is equal. In the

Table 3. Comparison of classical (variance-based) and perceived risk attitudes in each domain.

			Perceived-risk attitude: PRS	Perceived-risk attitude: PRA	
Gain	Risk attitude	RS	15	12	27 (33%)
		RA	8	46	54 (67%)
			23 (28%)	58 (72%)	81 (100%)
Loss	Risk attitude	RS	19	34	53 (57%)
		RA	5	35	40 (43%)
			24 (26%)	69 (74%)	93 (100%)
Both	Risk attitude	RS	21	30	51 (63%)
		RA	3	27	30 (37%)
			24 (30%)	57 (70%)	81 (100%)

Note: Values are numbers of respondents in each classification. Marginal percentages of total respondents in the given domain appear in parentheses. Using classical risk attitudes, most respondents are risk-averse for gains and risk-seeking for losses (row marginal percentages). Using perceived-risk attitudes, most respondents are perceived-risk-averse for both gains and losses (column marginal percentages).

both condition, 5 of these respondents chose to participate and 6 chose not to participate.

4. Discussion

In our experiment, the most common pattern of results was risk aversion in the gain condition and risk seeking in the loss condition – a replication of the classical reflection effect. The perceived-risk account of this effect – that people are perceived-risk averse in both conditions but differ in their risk perceptions across conditions – was also supported. Participation in the clinical trial (the higher-variance alternative) was perceived as riskier than non-participation by most respondents in the gain condition, but less risky by most subjects in the loss condition. In general, respondents who saw both framings behaved more similar to those in the loss condition, which suggests the relatively greater salience of losses than gains. (Kahneman and Tversky, 1979).

The one-trial between-subject design of this study is both a limitation and a strength. We do not have the ability to compare the same individuals' responses to clinical trials differing only in framing, or to fit models of risk perception or choice to these data. One must always be cautious in generalizing from the results of a single trial. On the other hand, the one-trial design limits the opportunity for method variance and more closely mirrors the actual decision situation faced by those who are offered a chance to enroll in a clinical trial. Moreover, the perceived-risk account has been supported in the past by within-subject studies, albeit in other contexts (Mellers, Schwartz, and Weber, 1997; Weber, 1997).

Our respondents were university undergraduates asked to make decisions about a clinical trial for a drug for high blood cholesterol. Although hypercholesteremia is uncommon in college-aged people, it is a common condition in the population at large and one that is likely to be familiar to college students either within their own family or through the many media messages related to cholesterol, diet, and cholesterol-lowering drugs. Moreover, because high cholesterol is a chronic and asymptomatic condition, subjects did not need to imagine any current functional impairment, and needed only to consider future health outcomes. No subjects indicated to the data collector that they did not understand the study materials. Although these findings should be replicated with other diseases and other subject populations (notably, patients who are actually living with the disease), there is reason to believe that these results are not anomalous and may generalize beyond our study.

Another possible concern is whether ratings of risk are actually merely ratings of attractiveness. Perhaps respondents are rating the attractiveness of each of the options and then choosing the more attractive option? This seems unlikely, however, given that the two risk ratings are made immediately before, and on the same piece of paper as, the choice. If respondents were really rating attractiveness, one would expect that all respondents would choose the option they had just rated as more attractive, and this does not occur. Weber, Anderson, and Birnbaum (1992) also found risk perception and attractiveness to be psychologically distinct constructs.

Neither the traditional account of the reflection effect nor the perceived-risk account are explanations of choices. Each merely classifies decision makers based on their choices between and/or perceptions of alternatives. Nor are their classifications necessarily inconsistent. One can be both variance-seeking and perceived-risk averse when low-variance outcomes are perceived as riskier. The addition of perceived risk as a measurable, if often latent, construct, may illuminate our understanding of the psychology of risky choice. Moreover, perceived risk attitudes may offer additional explanatory power as relatively stable traits that may moderate a wide range of medical decisions by patients.

In the larger realm of health policy, these results echo cautions about framing effects and other descriptive variance in the development of informed consent documents that have been expressed by others (e.g. Hux and Naylor, 1995). The spirit of providing patients with maximal information might suggest that outcomes ought to be presented in both gain and loss framings. However, because outcome framing as losses – even with concurrent framing as gains – may alter a prospective patient's decision about participation in a clinical trial in ways that may appear to suggest a risk-seeking attitude, its impact should be carefully considered. Otherwise,

many patients may be consistently perceived-risk averse, but their risk perceptions and, consequently, their choices, may be subject to manipulation.

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