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Payment expectations for research participation among subjects who tell the truth, subjects who conceal information, and subjects who fabricate information

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Abstract

Multiple models guide researchers’ payment practices but few studies have assessed subjects’ expectations for payment. Payments in excess of subjects’ expectations may result in undue inducement, while payments below these expectations may be associated with exploitation. Data on subjects’ payment expectations will help inform practices to avoid undue inducement and exploitation. This study examined subjects’ expectations for payment for common research procedures and explored the relationship between subjects’ honesty and payment expectations.

One-hundred subjects who participated two or more studies in the last year reported the minimum payment they expect for completing study procedures. They were also asked about their use of deception while screening for studies.

Subjects expected \$20 on average to complete the least risky and least burdensome procedure. Subjects’ expectations for payment consistently increased with greater procedure risks. Subjects who denied using deception to enroll in studies refused more procedures than subjects who reported using deception. Among subjects who used deception, the rate of procedure refusal increased with procedure risks, suggesting these subjects have some risk aversion and may act to protect themselves from undue inducement. Although subjects expect greater payments for more risky procedures, ethical considerations for limiting undue inducement may prevent researchers from meeting subjects’ expectations. Subjects who use deceptive practices appear to be more risk-tolerant than subjects who deny using deception; nonetheless, these deceptive subjects also exercise some risk aversion when they refuse higher-risk procedures. These subjects may be able to protect themselves from undue inducement by refusing procedures that exceed their risk tolerance.

Keywords

Research payment expectations; research risk tolerance; undue influence in research

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Introduction

Payment is a critical component of clinical research, yet most of the discussion of payment practices has focused on ethics and policies without including the subjects' payment perspectives. High levels of reimbursement could compromise subjects' ability to consent [1] and induce subjects to take risks that they would ordinarily refuse [2]. Because financial inducement may be more compelling to economically disadvantaged populations, overpaying research subjects may lead one segment of the population to assume disproportionate risks [3]. Multiple models exist as to guide payment practices: the Wage Payment Model provides subjects with a fair wage; the Market Model provides subjects with payments that are sufficient to enroll subjects given local market conditions; the Reimbursement Model provides reimbursement for expenses; the Token of Appreciation Model provides a small gift; and the Fair Share Model proposes paying subjects a percentage of the money that is owed to the investigator team [4,5,6]. Although following these models may provide some assurance that research subjects are appropriately compensated, debate has centered on which model of payment should be used, considering study characteristics (e.g., burden, potential for direct benefit), patient characteristics (e.g., vulnerability, socioeconomic status, age), and geographic characteristics (e.g., prevailing wage). What remains unaccounted for in this debate, however, are subjects' expectations regarding appropriate payments. Understanding subjects' perspectives could be instrumental in determining appropriate payments. Payment greatly above expectations may increase the risk of undue inducement while payment greatly below expectations of wage may result in feelings of exploitation [5]. Understanding expectations for payment could also provide some information about how subjects gauge study risks and apportion reimbursement expectations based on risk. Subjects' payment expectations are likely to increase for procedures involving higher levels of perceived risk.

Very few studies have directly assessed subjects' expectations for payment. Among the published studies that have assessed payment expectations, Slomka [7] found that low socioeconomic status, cocaine-using subjects expected at least \$20 (US) to take part in any research study. Breitkopf and colleagues [8] reported that women enrolling in a sexual health study expected reimbursement to be linked to inconveniences of participation, study risks, and the invasiveness of study procedures. Czarny et al. [9] found that when healthy volunteers were asked about reimbursement for four hypothetical studies, they expected greater payments for the burden of a study than for the risks of a study. Scherer et al. [10] reported that adolescents with no previous research experience expected lower payments for an asthma study than adolescents with previous study participation.

With such limited information about research subjects' expectations of payment, the present study was conducted to assess subjects' expectations for payment to undergo commonly used procedures that vary in risk. The present study was designed to explore subjects' willingness to identify a payment amount that would induce them to undergo these procedures vs. refusing to undergo the procedures at any payment amount. The present study also examined the relationship between the subjects' payment expectations and the subject's use of deceptive practices when enrolling in research.

Methods

One hundred subjects were recruited through newsprint advertisements and an online posting. An advertisement seeking ‘experienced research subjects’ was placed in two major newspapers in Boston (Boston Herald and Boston Globe) as well as a free newspaper (Boston Metro) distributed to bus and train commuters in Boston. This advertisement was also placed in the “volunteers” section of Craigslist. Clinical researchers across major academic institutions use all four of these media outlets when recruiting for studies in Boston. Subjects completed a brief telephone screening to determine whether they met the minimum criterion of participating in two or more research studies in the last year. Eligible subjects were invited to the clinic for the study interview. Subjects were consented if they met the requirement of having a blood alcohol concentration no greater than 0.020. Following the consent they completed a demographics form and were interviewed by research staff. The interview was designed to assess perceptions of a minimum payment for common research procedures and the lifetime use of deception while screening to enroll in studies (see Devine et al.[11] for a complete description of the interview). To assess payment expectations, subjects were asked “What is the minimum rate of pay you will accept to take part in the following types of study procedures” and presented with a list of commonly used research procedures (see Figure I). Subjects were able to name the payment they would expect as a minimum to undergo the procedure, or indicate that they would not undergo the procedure regardless of payment amount. To assess deceptive procedures, subjects were asked a series of questions to assess whether they conceal health conditions (see figure II for questions) or fabricate information about the disease being studied. Subjects were reimbursed 20 (US) for study completion. The Boston University Medical Center’s Institutional Review Board (IRB) approved all procedures used in this study and subjects provided informed consent in accordance with IRB requirements.

Analytic procedures

Values for reimbursement expectations and age are presented as mean values ($\pm$ standard error) unless otherwise indicated. The proportions for gender groups and rates of refusal are shown as percentage values. Based on subjects’ reported use of deceptive practices to enroll in studies, three “Subject Deception” groups were created to represent the different categories of lies that subjects use to improve the possibility of meeting study eligibility. Subjects who denied lifetime use of any deceptive practices to enroll in research studies were categorized as “Genuine” subjects. Subjects who reported past concealment of health information from researchers were categorized as “Concealers.” Subjects who reported to have fabricated a disease, exaggerated symptoms of a disease, or intentionally harmed themselves in order to meet eligibility criteria for a study were classified as “Fabricators.”

Dollar values for subjects’ payment expectations were normalized via transformation to natural log values. Procedures were grouped in Risk Pairs to provide a comparison of two procedures that have similar levels of time commitment and subject burden but differing levels of risk (see Figure III). One-way repeated measures analysis of variance was used to compare reimbursement expectations for Risk Pairs for the entire group of subjects. A second analysis was conducted using two-way repeated measures analysis of variance with

the risk level as the within-group factor and deception grouping as the between group factor. Finally, expected reimbursement for each of 8 procedures used in the Risk Pairs comparisons were compared across the three deception groups using one way analysis of variance. When asked about minimum rate of payment for undergoing a variety of study procedures, some subjects reported that they would refuse to take part in some procedures. The proportion of subjects refusing to participate for each of the eight procedures that were used in our Risk Pairs were examined to contrast rates of refusal between the Genuine group and the Fabricators group, and between the Genuine group and the Concealers group. These comparisons were made using chi-square tests or, when appropriate, the Fisher's exact test. Within-group comparisons were made for the proportion of subjects refusing to participate in a select few of the Risk Pairs examined in this study. This analysis was performed using repeated measures data to obtain Cochran-Mantel-Haenszel statistics. One subject was excluded from all analyses due to inconsistent responses across the interview.

Results

Demographic characteristics of subjects are shown in Table I. The mean age of this sample was 53. Greater than half of the sample was male (58% male, 42% female), and most subjects were either white (55%) or African American (37%). Roughly one-quarter (28%) of subjects reported completing a bachelor's degree or higher. Nearly two-thirds (62%) of subjects were retired, disabled, or unemployed, and more than half (58%) of subjects reported a household income below \$30,001. Based on questions about deceptive behavior, 19 subjects were categorized as "Genuine," 50 Subjects were categorized as "Concealers," and 32 subjects were categorized as "Fabricators" (N=32). There was a significant difference in age among these three groups [$F(2,96) = 5.7$; $p=0.005$]. Post-hoc comparisons showed that the mean age of Fabricators [$M= 46.9$ ($SE= 1.8$)] was significantly less than the mean age for the Genuine subjects [$M=59.4$ ($SE= 4.5$)] and the Concealers [$M = 54.3$ ($SE= 1.9$)]. There was also a significant difference in the gender proportions between the Genuine subjects (71% female) and the Fabricators (19% female, study [$X^2(1, N=50)= 12.8$, $p =0.0003$]. There was no significant difference in gender proportions between the Concealers (48% female) and the Genuine subjects. The majority (55%) of subjects in this study participated in 2-5 studies in the past year. One-fifth of subjects (20%) reported participating in 6-10 studies in the past year and one-quarter of subjects (25%) reported participating in more than 10 studies in the past year. More than two-thirds (69%) of the subjects reported participating in a study that included taking a medication or vitamin. Greater than one-third (35%) reported participation in a study involving counseling or psychotherapy. Half of the subjects (51%) in the sample have participated in a study to treat a problem or condition that they have. The average lifetime earnings from previous study participation among the subjects in this study was \$9,809.

Mean values for subjects' expectations for minimum payment to complete common research procedures for the entire sample of subjects are shown in Table II. Across the entire sample of subjects, expectations for reimbursement increased in relation to the increasing risk of study procedures. For example, there were significant differences in payment expectations between proving a urine sample ($M=\$24$, $SE= 3$) and providing a blood sample ($M=\$31$, $SE=3$), [$F(1,94)=43.1$; $p<0.0001$] and also between providing a blood sample and providing

a tissue sample [$M=\$86$ ($SE=9.3$)], [$F(1,89)=118$; $p<0.0001$]. Subjects reported expectations of \$97 ($SE=17$) for taking an FDA-approved medication for one day. This expectation for payment jumped to \$125 (21) for taking an investigational medication for one day [$F(1,71)=37.6$; $p<0.0001$]. A similar difference was observed between subjects' expectations of payment for taking an FDA-approved medication for 12 weeks ($M=\$1,151$, $SE=183$) vs. expectations of taking an investigational medication for 12 weeks ($M=\$1,867$, $SE=323$), [$F(1,69)=22.6$; $p<0.0001$]. Interestingly, expectations of payment for a single day of taking FDA-approved or investigational medication during the course of a 12-week trial were dramatically less (\$14 per day for FDA-approved and \$22 per day for investigational) than expectations when taking the medication for only a single day (\$97 and \$125 respectively). Relative to taking an FDA-approved medication for 12 weeks [$(M=\$1151, (183))$], subjects expected substantially less for taking part in weekly one-hour study visits for 12 weeks ($M=\$412$, (31), [$F(1,81)=27.8$; $p<0.0001$].

When expectations for reimbursement were examined with deception grouping as a factor, similar results were found. For each of the five Risk Pairs (figure III we examined, the within-subject factor for risk levels was found to be significant (see Table III). Neither the group factor nor the group x risk level interaction, however, were found to be significant. Thus, for a given comparison of risk levels, deception grouping did not appear to significantly affect reimbursement expectations. Finally, reimbursement expectations across deception groups for each of the 8 procedures used for the Risk Pair comparisons did not reveal significant differences among the groups.

When asked about minimum rate of payment for undergoing a variety of study procedures, some subjects reported that they would refuse to take part in some procedures irrespective of payment amount. This rate of refusal ranged from 0% for completing an hour of questionnaires to 30% for taking an investigational medication for 12 weeks (see Table II for rates of refusal across all study procedures for the entire study sample). In general, there is a correspondence between the level of risk for a procedure and percent of subjects who refuse to undergo a procedure (see Table III). The percent of refusal was significantly less for Fabricators than the Genuine subjects for 5 of the procedures. The rate of procedure refusal was also significantly less for the Concealers than for the Genuine for four of the procedures.

Rates of refusal were compared within group for Concealers and Fabricators to determine whether these groups evidenced some aversion to risk between Risk Pairs. Genuine subjects were excluded from these analyses as it is clear from the between group findings that this group exercises risk aversion by refusing a higher percentage of procedures than the other two groups. Among Concealers, there was a significant difference in the rate of refusal for taking an FDA-approved medication for one day (8%) and the rate of refusal for taking an investigational medication for one day (24%). The rate of refusal for 12 weeks of FDA-approved medication and 12 weeks of investigational medication was not significantly different among the Concealers. Among Fabricators, there was a significant difference in the rate of refusal for taking an FDA-approved medication for one day (0%) and the rate of refusal for taking an investigational medication for one day (19%). Among Fabricators, there was also a significant difference in the rate of refusal for taking an FDA-approved

medication for 12 weeks (3%) and the rate of refusal for taking an investigational medication for the same length of time (22%).

Discussion

Consistent with Slomka's findings [7], subjects in this study expected no less than \$20 on average to take part in any study procedure. Rates of reimbursement for some procedures are greater than the recommendations made by Dominguez et al. [12], who published payment guidelines based on historical rates of payment at a large NIH Clinical Center. For example, subjects in the present study expected an average payment of \$31 for a blood sample; Dominguez and colleagues recommended an average payment of \$23. Subjects in the present study expected an average of \$86 to provide a tissue sample; Dominguez and colleagues recommended an average payment of \$56. The location of studies, cost of living, competing studies, and availability of volunteers (i.e., Market conditions) may all impact the rate of study payments which could explain the difference in expectations in this sample and actual payment data reported in Dominguez's study.

The results of this study indicate that subjects expected to receive higher payment for riskier procedures than for less risky procedures. With recent changes in guidance from the Office for Human Research Protections (OHRP) for minimizing undue influence in the consent process (45 CFR 46.116), it is permissible to pay subjects greater amounts for more risky study procedures but payment should not be considered a benefit of participation by Institutional Review Boards [13]. While increasing payments to compensate subjects for the risks they take during study participation seems to be a method for reducing the potential of exploiting subjects, the inherent problem is determining how much compensation is fair vs. becoming an undue inducement to participate. One method for determining fair compensation that does not present the risk of undue inducement is to use survey data like that collected in the present study. For example, the average expected payment for taking an investigational medication for one day was \$125, but two subjects reported that they would not do this for any less than \$1,000. This expectation of \$1,000 is likely to be an "undue inducement" amount given how far it is from the average expectation. Examining the distribution of subjects' payment expectations for specific study procedures may inform researchers' decision-making when setting payment levels.

Expectations for payment did not differ significantly between subjects who answered screening questions truthfully versus subjects who used concealment and fabrication strategies (lifetime) when screening for entry into a study. It appears that subjects who use deceptive strategies expect no more or less in study payments than subjects who do not use deceptive strategies. Some subjects who use deceptive practices, however, appear to be more risk-tolerant than subjects who do not use deceptive practices. As a group, subjects who reported using fabrication had lower rates of procedure refusal than Genuine subjects for undergoing a blood draw and for taking any medication (FDA or investigational) over periods of 1 day or 12 weeks. Interestingly, although these subjects are more risk-tolerant than Genuine subjects, they also exhibit some risk aversion. Among Fabricators, significant differences between the rate of refusal for taking FDA-approved medication and taking investigational medication were evident for one-day administration and 12-week

administration. Contrary to concerns that subjects may be unable to protect themselves against undue inducement, this study suggests that even the subjects who enroll in multiple studies using deception to bypass eligibility restrictions have the intention to refuse procedures which exceed the risk or discomfort that they are willing to assume.

Limitations

The scope of research procedures that were presented to subjects may limit the generalizability of these findings. For studies that use specialized procedures or other variations of procedures that were not assessed in the present study (e.g., MRI with contrast), expectations for payment reported in this study may not be relevant to inform future payment practices. Future studies of payment expectations should include a wider range of commonly used research procedures. It is possible that subjects' expectations for payment are influenced in part by the prospect of direct benefit from study participation. The procedures assessed in the present study were presented a la carte without the context of a study that might have some prospect of benefit. Additional research in this field could examine expectations of payment in the context potential for benefit (direct benefit to subjects only, benefit to science only, or both) to understand how benefit may impact subject's expectations of payment. Another limitation of this study is in the sampling across groups: deception groups were not balanced with respect to the age and gender of subjects, with the mean age of subjects being slightly lower in the Fabricators group than in the other two groups and a larger proportion of women being in the Genuine subjects group than in the Fabricators group. Balancing age and gender across group in the sampling would provide better assurance that these demographic variables skew the study findings. Payment expectations may be influenced by regional market conditions as well. This could limit the generalizability of payment expectations to similar geographic markets with academic research being conducted within an urban environment.

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What is the minimum rate of pay you will accept to take part in the following types of study procedures:

- _____ One hour of interviews
- _____ One hour of questionnaires
- _____ Provide a single urine sample
- _____ Provide a single blood sample
- _____ Provide a single saliva (spit) sample
- _____ Provide a single tissue sample (e.g., skin biopsy)
- _____ Take an FDA approved medication for one day
- _____ Take an investigational medication for one day
- _____ Spend an overnight in a lab or hospital
- _____ Eat a special diet for one day
- _____ Abstain from food for 6 hours
- _____ Receive one hour of counseling
- _____ Undergo a 30 minute MRI exam
- _____ Attend one-hour weekly study visits for 12 weeks
- _____ Spend one week hospitalized
- _____ Take an FDA approved medication for 12 weeks
- _____ Take an investigational medication for 12 weeks

Figure I.
Interview questions to assess subjects' payment expectations

Concealing Information

In this next section I'm going to ask you some questions about strategies people sometimes use to get into studies. As you may know, many studies have strict criteria for who is allowed into the study. Sometimes people will hide information or provide false information in order to get by some of these rules. I am going to ask you questions about whether you have done this in the past. Remember that your answers will not be associated with your name. Your honesty about this is really important to us.

I am going to start by reading a list of types of information that people sometimes withhold – let me know if you have ever done this because you knew it would keep you out of a study:

YES NO Health problems

YES NO Mental health problems

YES NO Your participation in another study

YES NO Use of other prescribed medicines

YES NO Recreational drugs

YES NO Pending legal issues

YES NO Your housing situation

YES NO Your use of alcohol

YES NO Your family history

YES NO Any other information? _____

Fabrication Information

Have you ever exaggerated the symptoms of your health condition in order to gain entry into a study?

Have you ever pretended to have a health problem in order to qualify for a study?

Have you ever done intentional harm to yourself in order to qualify for a study?

Have you ever given researchers false information about your symptoms that are the primary focus of the study?

Figure II.

Interview questions to assess subjects concealing information and fabricating information

Risk Pair	Relative risk	
	Low	High
1	Urine collection	Blood collection
2	Blood collection	Tissue collection
3	1-day taking FDA approved medication	1-day taking an investigational medication
4	12 weeks taking an FDA-approved medication	12 weeks taking an investigational medication
5	12 weeks of once-weekly study visits	12 weeks of taking an FDA-approved drug

Figure III.
Researcher procedures grouped into Risk Pairs

Table I**Subject Demographics**

	n	%
Gender		
Male	57	58
Female	42	42
Hispanic	6	6
Race		
White	54	55
Black, or African American	37	37
Other	8	8
Education		
No schooling completed	3	3
12th grade, no diploma	7	7
High school graduate or GED	22	22
Some college credit but no degree	30	30
Associate degree	9	9
Bachelor's degree or higher	28	28
Past 30 Days Employment		
Unemployed	32	32
Retired/Disabled	29	29
Part-Time	23	23
Full-Time, 35+ hrs/week	11	11
Homemaker	2	2
Student	1	1
In controlled environment	1	1
Household income		
\$0 - \$15,000	36	36
\$15,001 - \$30,000	21	21
\$30,001 - \$45,000	18	18
\$45,001 - \$60,000	12	12
\$60,001 - \$75,000	6	6
\$75,001 or greater	6	6

Table II

Mean reimbursement expectations and refusal rates for common research procedures.

Procedure	Mean (SE)	Median	Range (US \$)	Percent Refusal
One hour of interviews	20 (1)	\$20	\$0-100	0%
One hour of questionnaires	20 (1)	\$20	\$0-75	0%
Provide a single urine sample	24 (3)	\$20	\$0-200	0%
Provide a single blood sample	31 (3)	\$25	\$0-200	4%
Provide a single saliva sample	23 (2)	\$20	\$0-100	0%
Provide a single tissue sample (e.g., skin biopsy)	86 (9)	\$50	\$1-500	7%
Take an FDA approved medication for one day	97 (17)	\$50	\$0-1,000	11%
Take an investigational medication for one day	125 (21)	\$75	\$10-1,000	28%
Spend an overnight in a lab or hospital	175 (19)	\$100	\$30-1,500	7%
Eat a special diet for one day	52 (4)	\$50	\$0-200	1%
Abstain from food for 6 hours	42 (3)	\$33	\$0-150	3%
Receive one hour of counseling	32 (3)	\$25	\$0-200	3%
Undergo a 30 minute MRI exam	81 (9)	\$50	\$0-500	7%
Attend one-hour weekly study visits for 12 weeks	412 (31)	\$300	\$0-1,800	1%
Spend one week hospitalized	1,022 (109)	\$700	\$0-5,000	10%
Take an FDA approved medication for 12 weeks	1,151 (183)	\$550	\$30-10,000	17%
Take an investigational medication for 12 weeks	1,868 (323)	\$1000	\$0-13,500	30%

Table III

Mean (SE) reimbursement expectation and percent of subjects who would refuse a procedure by deception grouping for 8 procedures.

Procedure	Deception Grouping					
	Genuine subjects		Concealers		Fabricators	
	Payment amount	Percent Refusal	Payment amount	Percent Refusal	Payment amount	Percent Refusal
Urine Sample	20 (3)	0%	27 (5)	0%	21 (2)	0%
Blood Sample	24 (3)	12%	34 (5)	4%	29 (3)	0% *
Tissue sample	86 (21)	18%	83 (13)	2% *	91 (17)	9%
FDA-approved medication for 1 Day	134 (87)	41%	89 (23)	8% *	96 (18)	0% *
Investigational medication for 1 Day	175 (118)	53%	124 (29)	24% *	112 (18)	19% *
FDA-approved medication for 12 weeks	1,012 (442)	41%	1,387 (313)	18%	896 (217)	3% *
Investigational medication for 12 weeks	1,686 (1,196)	53%	1,929 (428)	27% *	1,836 (548)	22% *
One-hour weekly study visit -12 weeks	364 (75)	6%	411 (45)	0%	439 (54)	0%

* p< 0.05 for comparison with the Genuine group.