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Perceptions of Reimbursement for Clinical Trial Participation

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Abstract

A greater understanding of participant views regarding reimbursement will help investigators plan studies that have better potential for reaching target enrollment, maximize efficient recruitment, maintain scientific integrity, and enhance retention over time. As part of a clinical trial in the area of sexual health, healthy women's perceptions of reimbursement for research participation were investigated. Semi-structured, audio-recorded, qualitative interviews were conducted immediately upon women's completion of the clinical trial to enable a participant-driven understanding of perceptions about monetary reimbursement. Audio-recordings were transcribed and analyzed using framework analysis. Women (N = 30) had a mean age of 29.5 ± 5.7 years (range 22–45 years). Sixty-three percent of participants (n = 19) were non-Hispanic (white n = 13, black n = 4, and Asian n = 2), while the remaining were Hispanic (n = 11). Seventy-three percent (n = 22) reported previous participation in research. In general, women viewed reimbursement as a benefit to research participation, the amount of which should reflect time, the inconvenience to the research subject, and the potential for unknown risks in the short- and long-term. They believed reimbursement should take into account the degree of risk of the study, with investigations of experimental products offering greater reimbursement. Women believed that monetary reimbursement is unlikely to coerce an individual to volunteer for a study involving procedures or requirements that they found unacceptable. The results of this study can be used to provide guidance to those planning and evaluating reimbursement for research participation.

Keywords

incentive; risk; subject payment; clinical trial; reproductive health; reimbursement; coercion; qualitative interviews

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Without research involving human subjects, new knowledge regarding prevention and treatment of conditions that can impair health will not be acquired. However, researchers must engage humans as research participants in ways that are respectful, just, and minimize harm (U.S. Department of Health, Education, and Welfare, 1979). In planning studies, investigators must consider whether monetary reimbursement should be offered and, if so, determine an appropriate amount. Published guidelines generally agree that in order to protect human subjects, monetary incentives should be limited to compensation for time, lost earnings, travel, and other expenses incurred in taking part in a study; that no payment should be given for the assumption of risk; and that subjects may be paid or otherwise compensated for inconvenience (Council for International Organizations of Medical Science [CIOMS], 2002; Dickert, Emanuel, & Grady, 2002; Fry et al., 2006; National Institutes of Health, Office of Human Subjects Research, 2006). According to international guidelines, compensation should be evaluated for appropriateness in light of cultural traditions.

Financial compensation is a strong motivator of research participation (Bigorra & Banos, 1990; Fry & Dwyer, 2001), conveys the message to participants that researchers value their time, and contributes to successful recruitment and retention (Bentley & Thacker, 2004; Halpern et al., 2004; Slomka et al., 2007). In addition, monetary reimbursement to participants who are patients is believed by some to counter the therapeutic misconception, i.e., that an unproven treatment is, in fact, effective (Dickert & Grady, 1999). Moreover, being able to retain participants in studies may enhance scientific integrity and ability to monitor risks. Empirical studies by Festinger and colleagues among drug-using populations have shown that higher magnitude payments in cash may be effective in retaining participants in longer term follow-up without resulting in new or increased drug use or perceptions of coercion by study participants (Festinger et al., 2005; Festinger et al., 2008). Finally, study payment has been shown to imply information about risk whereby subjects paid greater attention to the description of potential risks when payment amounts were greater (Cryder et al., 2010).

Alternatively, financial compensation can raise concern over “undue inducement,” or offering reimbursement amounts sufficiently excessive to lead individuals to consent to research participation against their own better judgment (CIOMS, 2002). This issue is of particular concern with vulnerable populations. However, there is no evidence to support this concern (Bentley & Thacker, 2004; Halpern et al., 2004), and in fact, one study challenged the view that economically disadvantaged individuals are less willing or able to consider the risks of participation when monetary reimbursement is involved, and described payment for research participation as just one part of the “informal economy” in poor communities (Slomka et al., 2007). Monetary payments can influence individuals’ propensity to deny performing restricted activities before or during a study (Bentley & Thacker, 2004); it is also possible that participants believe they must adhere to trial demands to receive reimbursement and thus over-report adherence. Clearly, these instances could negatively impact scientific integrity.

Few studies have explored potential emotional or logistical issues associated with research participation in healthy volunteers as they relate to reimbursement (Ripley et al., 2010), yet phase I trials typically seek to enroll a small number of low-risk, healthy participants, who will not otherwise benefit from participation. It therefore seems important to understand perceptions of reimbursement among this group in order for investigators to plan studies that maximize efficient recruitment, achieve enrollment goals, maintain scientific integrity, and enhance retention. We explored healthy women’s perceptions of reimbursement as they took part in a phase I clinical trial designed to test a new vaginal imaging method. The trial involved potential emotional issues or procedures which could be construed as

uncomfortable or embarrassing (e.g., gynecological exams, screening for sexually transmitted infections [STIs]) and logistical issues including behavioral requirements that may be perceived as inconvenient or require negotiation/explanation (e.g., abstinence from intercourse, use of a vaginal gel).

Method

Women were recruited to participate in a clinical trial designed to evaluate the use of a non-invasive method of imaging, i.e., Optical Coherence Tomography (OCT), as a potential safety tool in the development of vaginal microbicides (Vincent et al., 2008; Vincent et al., 2009; Vincent et al., 2011). Vaginal microbicides are products used intravaginally by women that are intended to reduce acquisition of STIs. As part of the trial, serial face-to-face interviews were conducted to understand participants' research experiences; at the final interview, perceptions regarding reimbursement were explored.

Upon review and approval by the University of Texas Medical Branch Institutional Review Board (IRB), participation was solicited using flyers posted on the medical campus, web-based announcements, and word-of-mouth. Study procedures included gynecologic exams, collection of pooled vaginal secretions, colposcopic examination, vaginal imaging using OCT, and audio-recorded interviews at each of three study visits. In addition, participation involved insertion of a vaginal gel twice daily for 5.5 days and abstinence from vaginal intercourse for approximately 16 days. Reimbursement amounts were proposed by the investigators and approved by the IRB at a rate of $100 for the screening visit (about 60 minutes' duration) and $125 each for visits 1–3 (about 60–90 minutes each). Reimbursement was dispensed as cash at the end of each visit. Parking tokens were provided to participants as needed.

General inclusion criteria for the trial were: healthy female, 18–45 years of age, pre-menopausal (defined as having regular menstrual cycles), considered low-risk for STIs (based on participant self-reported characteristics of herself and her sexual partner), willing to discontinue use of vaginal products (e.g., douches, vaginal moisturizers, tampons) and deodorant pads and to abstain from intercourse for 48 hours prior to the first study visit until completion of the study. The informed consent process involved a verbal presentation of the study's purpose, affirmation that the activity is research, description of study procedures, risks, benefits, anticipated time commitment, reimbursement, reasons for withdrawal by the investigators, and an opportunity to ask questions before written consent was obtained. The boundaries of confidentiality were outlined and prospective participants were reminded of the voluntary nature of research participation. Women subsequently completed demographic and sexual history forms and received medical evaluation for additional exclusion criteria.

Semi-structured, qualitative interviews conducted at the end of the last study visit (visit 3) explored participant perceptions of reimbursement. The interview guide included the questions: "How did you feel about the reimbursement for this study?"; "Did you feel the reimbursement provided was adequate?"; "How do you feel about reimbursement if the product you were using was experimental, i.e., never been tested in humans before?"; and included probes (e.g., "Can you tell me more about that?"). The questions were developed by the investigators and guided by a previous microbicide study among males (Holmes, Maher, & Rosenthal, 2008; Rosenthal, Holmes, & Maher, 2009). The term "reimbursement" was used instead of "remuneration," "incentive," or "payment" to be consistent with the language used in the informed consent document. Interviews were audio-recorded, transcribed verbatim, and analyzed using framework analysis. Framework analysis incorporates a priori themes as coding categories to address predetermined issues of interest while accommodating de novo, participant-generated themes (Dixon-Woods, 2011; Ritchie

& Spencer, 1994; Srivastava & Thomson, 2009). A priori interests related to attitudes toward reimbursement, adequacy, and consideration of reimbursement with regard to experimental agents. Familiarization with the data began by having three individuals independently read the transcripts and refer to interviewer notes; transcripts were annotated to identify de novo themes (new, participant-generated concepts) and characterize key issues and concepts that were used to code the data. Upon discussion and agreement of primary themes, electronic files were generated to reflect each theme using content from the transcripts. Extracted interview content was labeled with participant ID and visit number, and subfiles within each theme were created as appropriate. This process was initiated while the interviews were ongoing to enable the interviewer to explore new concepts with future participants that required further understanding. This was allowed, given that the purpose was to understand reimbursement from a participant-driven perspective. Coding and interpretation of the qualitative data was an iterative process, concluding upon consensus and saturation of the findings.

Results

Participant Characteristics and Setting

Participants (N = 30) had a mean age of 29.5 ± 5.7 years (range: 22–45 years). Sixty-three percent (n = 19) were non-Hispanic; these women identified their race as white (n = 13), black (n = 4), and Asian (n = 2). Women of Hispanic ethnicity (n = 11) identified as Mexican (n = 5) and “other” (n = 6). The sample was educated, with 26 out of 30 participants reporting at least some college education. At enrollment, 70% of women were married (n = 10) or in a serious relationship (n = 11), one woman was in a casual relationship, and the remainder (n = 8) were not in a relationship. Seventy-three percent (n = 22) of the sample reported previous research participation. A majority of participants (n = 19) worked at the medical center, five were medical students, and the remaining participants were neither associated with medicine nor the medical center.

Interviews were conducted in private rooms on a specialized clinical research unit located at the University of Texas Medical Branch. Twenty-eight out of 30 interviews (93%) reported in this paper were conducted by the same interviewer, while two interviews were conducted by a second interviewer.

Overall Attitude Regarding Reimbursement

Nearly all (n = 28) women indicated that the study reimbursement was adequate, using the descriptors “fair,” “reasonable,” and “very good.” Two women stated that reimbursement should have been more, with one suggesting $200 per visit. Participants used words such as “paid,” “stipend,” “incentive,” and “income” to refer to monetary reimbursement, and one woman indicated that she “leased her vagina to science.” Views on reimbursement reflected the type and timing of reimbursement. Specifically, cash was preferred, as this woman stated: “I like that you give cash instead of a check because … mailing the checks was bad, it always tends to get screwed up ….” With regard to timing, another woman stated: “a lot of studies don’t give the reimbursement until the very end … this was nice, because it was every time we came and it was kind of like, oh, you kind of look forward to coming back the next time.”

Many participants worked in research settings; thus, knowledge about how reimbursement is decided and approved was evident. For instance, one woman stated: “Ya’ll should ask for more … whoever writes the grants should request a bigger stipend to give the participants.” Another woman stated: “I’m not really sure because I have done other studies where you

reimburse and I know you have to go through the IRB to get approval. So I guess it's up to the PI and who is giving them the grant …."

Participants' responses indicated that the amount of reimbursement should be related to known inconveniences and unknown risks, and viewed reimbursement as unlikely to be coercive and as a benefit of participation.

Known Inconveniences

Participants differentiated between predicted or "known" inconveniences that were outlined in the consent form (e.g., side effects of vaginal gel use, potential embarrassment) and risks that were unknown or unanticipated. With regard to known inconveniences, participants focused on the time involved and various aspects of the study procedures ("hassle," perceived invasiveness and familiarity), including physical and emotional aspects of participation. The majority of respondents felt that reimbursement should be greater when research participants are asked to accept unknown risks.

With regard to reimbursement for time, participants considered travel time to the research unit, time spent at study visits, time off from work to attend visits, and time spent at home using the vaginal product, including the need to remember to do it. One woman stated: "… you are at home with the product and inserting that twice a day, so … taking time out and remembering to be good about taking your doses. I think that would be the main thing to be compensated for. I mean, yes, the time to come in and to do the exam, but that is really not that bad. It's just, the remembering."

Participants viewed the inconvenience or "hassle" for this study as generally relating to use of the vaginal product. Women believed that greater reimbursement should accompany increased inconvenience, as this woman stated: "So the first visit is basically just like a doctor's exam, normal, you know, Pap smear. But then … you have to take into account the going home, using the product was a bit of an inconvenience, especially with the leakage and how messy it was. So maybe those visits around that, maybe bump up the compensation a little more."

Reimbursement was also evaluated by participants with respect to the invasiveness of the study procedures, with perceptions of invasiveness being reduced when study procedures were familiar, such as a Pap test and pelvic exam. One woman commented: "I think the amount you guys are giving is sufficient for the type of procedure and how invasive the procedure is … it's not like you're cutting into someone" and "I feel like it [the reimbursement] was too much actually, for just getting an exam that you normally get." Another woman stated: "so the only thing is just … taking things from me like fluid samples and taking pictures … I felt like it [the reimbursement] was a justifiable amount."

Women's experience of "emotional risk" was individualized. For instance, this participant stated that some women might be embarrassed by the gynecologic exams, and reimbursement should take this into account: "Well, honestly, it depends on how shy a person is. To me, it was a great amount of reimbursement for what I had to do. [My friend who is more timid] … she might need some more, you know what I mean?" Similarly, another woman stated: "The reimbursement is good, but … if you reduced it a whole lot, I don't think you'll get anyone in 'cause nobody is going to come in and sit through a gynecological exam for ten, twenty dollars an hour …."

Two women related reimbursement to the abstinence requirement, as one stated: "It's an easy study but at the same time … for you not to have sex … I think that at least somewhat compensates for that part. So if it was less then it might not be as attractive … if it's not

compensating for what you're having to not do …." A third participant stated that she shared the reimbursement with her partner because they could not have sex.

Unknown Risks

When participants were asked what should determine the amount of reimbursement for a study involving an experimental product, risks that are unknown at the time of participation were mentioned. The idea that harmful effects of a study procedure or product could be discovered in the future was worrisome and a factor in evaluating reimbursement. For example, one woman stated: "Uh, like not knowing long-term effects of something I'm about to use in my body. That's a huge risk." Women considered both short- and long-term risks, and physical as well as emotional risks. For example, when considering a study involving an experimental product, a 28-year-old participant stated: "I'd be a little more hesitant, because … I know with, like, my age group people are concerned about babies and what it's going to do to babies or to them having a baby …."

Overwhelmingly, women commented that reimbursement for studies involving experimental agents should be greater. "If the product is experimental, the reimbursement should be more … Because you're basically a guinea pig, so you're putting yourself at risk for something, like I said, long term. Maybe double the amount." One woman stated that she would not participate in a study using an experimental product (regardless of reimbursement), while a second woman indicated she would "think twice;" in contrast, another woman admitted that she did not remember that the product she was using was not experimental.

Views on Coercion

Women commented that it was unlikely that monetary reimbursement could be coercive: "… if it's not something you're interested in, it doesn't matter how much they offer you, you're not going to do it. You could probably offer me $1,000 to do a muscle biopsy study, and I don't want to do it. I don't want somebody cutting my leg open … if it's not something you're comfortable with it doesn't matter how much money they'll offer …" and "If you hate gynecologic exams it's not going to induce you to do it … And I think especially when it comes to like reimbursement if it's not something you're interested in, it doesn't matter how much they offer you, you're not going to do it." The only participant who gave any indication that monetary reimbursement could be coercive provided an extreme example seeming to suggest that coercion was not a major concern: "… I wouldn't do it if it was an experimental product. I don't know …. Like I'd have to be in a really bad rut and it would be, like, a thousand or over … Unless I … didn't have food. Then I would do it."

Reimbursement as a Benefit to Participation

Women viewed monetary reimbursement as a benefit of trial participation, not unlike learning something new, getting free medical screening, or advancing science. As one woman stated: "It's really nice … It's not like we're getting ripped off. I mean, it's just an exam that you go and have done and the fact that you do the STD screening and the pregnancy testing, like that, it really helps out … I feel compensated, well-compensated." Overall, women did not seem to consider trade-offs between various benefits to participation whereby a lower amount of reimbursement could be offset by an array of other benefits, with only one woman mentioning receiving screening test results in the context of evaluating the adequacy of reimbursement.

Discussion

Participants in this study offered several perceptions that depart from conventional wisdom among the research community with regard to monetary reimbursement. The first of these perceptions departs from NIH internal guidelines and the position of the Office for Human Research Protections (OHRP) that monetary payment should not be considered a benefit to be gained from research participation (National Institutes of Health, Office of Human Subjects Research, 2006), as many participants made statements implying that financial reimbursement was a benefit to trial participation. Overall, little evidence of a trade-off between benefits was apparent whereby less reimbursement was acceptable for studies with greater individual benefit.

In contrast, participants did seem to perceive a trade-off between both unknown risks and known inconveniences and reimbursement. Specifically, women did not relate the amount of reimbursement to the known risks that were described during the informed consent process; rather, women believed reimbursement amounts should reflect the unknown risks of participation (short- and long-term). This perception was highlighted in women's comments regarding studies testing experimental products, where higher reimbursement was expected by nearly all women. These findings, together with others suggesting that participants infer greater risk in higher-reimbursing studies (Cryder et al., 2010), lend further support to a linkage between perceived risk and reimbursement among research volunteers. These findings should provide strong encouragement for investigators to engage in careful thought and planning regarding reimbursement amounts.

A second perception relates to the adequacy of reimbursement, and what it should reflect. It is not uncommon for investigators or IRBs to focus on time, study procedures, and behavioral requirements (e.g., attendance, fasting). Indeed, while most women related reimbursement amounts to events (e.g, pelvic exams) occurring during the study visits, several did refer to research activities (i.e., vaginal gel use) or requirements (i.e., abstinence) that occurred outside of the visits. These findings are consistent with recommendations by Ripley et al. (2010) regarding reimbursement, and suggest that investigators should consider behavioral expectations outside of the study visit when determining reimbursement amounts, as prospective participants may include them in their decision making.

Third, our results have bearing on continuing debates regarding reimbursement, coercion, and "undue influence" (Emanuel, 2005). Our interview data are consistent with literature suggesting that monetary reimbursement can motivate participation but cannot, by itself, be coercive (Bentley & Thacker, 2004; Festinger et al., 2005, 2008; Halpern et al., 2004) and that using incentives to recruit and retain research subjects is innocuous under most circumstances (Grant & Sugarman, 2004). Specifically, women believed that money could not coerce an individual to volunteer for a study involving procedures or requirements that they found unacceptable. However, participants clearly stated that even women who are interested in research are not going to undergo research procedures, take time off from work, or adhere to challenging demands in the absence of reasonable reimbursement.

Finally, in contrast to practices by investigators and IRBs that typically evaluate reimbursement for a research protocol on a "case-by-case" basis, participants appear to apply a "community standard" when evaluating reimbursement; that is, they consider reimbursement for one study relative to reimbursement amounts offered for other, similar studies at the same institution. Many participants in this study were employed in research labs or had previously enrolled in studies; several women specifically referred to other studies when prompted to evaluate the reimbursement for the current study. This observation

suggests that community standards are relevant when investigators are deciding upon remuneration amounts.

This investigation is limited in that interviews were conducted among a small, convenience sample of healthy women, many of whom were affiliated with the institution through employment or education, and who ostensibly found reimbursement acceptable. On the one hand, the prior research experience of the sample may be a strength, as the perceptions that were captured likely represent the type of individuals who serve as healthy volunteers, particularly in phase I studies. On the other hand, the experience of the sample could be a weakness in that the perceptions of "research savvy" participants may differ in important ways from other types of research subjects, thus limiting the generalizability of our findings. In addition, perceptions of men, perceptions of women who do not tend to participate in research, or who found the reimbursement amount unacceptable were not represented. We did not assess other participant characteristics of potential importance to perceptions of reimbursement such as income, occupation, or number of previous studies in which they participated, which may have been insightful. Finally, the interview questions regarding reimbursement were not the main focus of the trial, and we neither manipulated level of reimbursement nor queried women's willingness to participate in the absence of reimbursement. Although standard interviewing techniques were used, it is possible that women, many of whom were employed in research labs, engaged in "impression management," as they depicted their attitudes toward reimbursement in largely positive terms. This seems unlikely, however, given the candid, sometimes negative comments that were expressed in other parts of the interview regarding the clinical trial procedures and noncompliance with study demands (Radecki Breitkopf et al., in press). Finally, the placement of the questions regarding reimbursement in the final interview when participants would have no more contact with the investigators further minimized the influence of socially desirable responding.

Best Practices

Decisions regarding reimbursement are exceedingly important and potentially influence the success of scientific studies including clinical trials. Investigators are cautioned that what constitutes appropriate reimbursement may differ as a function of individual participants' experiences and community standards. Furthering this research by capturing the views of participants with different health status or socioeconomic backgrounds and including a variety of research communities seems worthwhile. While the data seem reassuring regarding reimbursement and lack of coercion, it is concerning that participants may infer risk from reimbursement and, at the very least, link reimbursement to risk. These findings suggest that investigators could inadvertently communicate the wrong information about risk by offering low or no reimbursement.

Research Agenda

It is believed that reimbursement which appropriately reflects the inconvenience or difficulty associated with study requirements may lead to greater compliance with trial demands and greater retention over time, although more empirical studies are needed. Recent analysis of research payments suggests that, in some cases, reimbursement failed to adequately compensate calculated costs of participation (Ripley et al., 2010). Guidelines based on evidence could be developed by conducting additional, similar studies, by transparency in reporting reimbursement details in scientific publications, by benchmarking reimbursement practices against similar research (Fry et al., 2006), and by IRBs assisting investigators in developing community standards.

Educational Implications

In general, determination by an independent review panel that a research study has a favorable risk/benefit ratio is relied on to insure that reimbursement is not harmful (Brody, 1998). However, little guidance exists for determining the amount of reimbursement that is appropriate for a given study, and the use of “rules of thumb” is common (Dickert, Emanuel, & Grady, 2002). Several models have been proposed, including the market, wage-payment, and reimbursement models (Dickert & Grady, 1999), yet none have been formally adopted or recommended by research regulatory bodies. IRBs ultimately must approve reimbursement amounts after evaluating factors including the vulnerability and autonomy of the subjects, the time requirements for participation, and other expenses incurred while attending study visits. Qualitative data obtained from healthy volunteers suggest that the reimbursement models and the judgment by IRB members may neglect to account for research participants’ subjective experiences in important ways and over-emphasize concerns (e.g., coercion or undue influence) that are rejected by participants themselves.

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Biographies

Carmen Radecki Breitkopf has expertise in the regulations and protections governing research involving human subjects based on her previous work as an IRB Director. She is a psychologist with a particular interest in attitudes and decision making surrounding preventive health behaviors.

Melissa Loza is a clinical research coordinator who assisted in the development of the interview guide and conducted the qualitative interviews for this clinical study.

Kathleen Vincent is an obstetrician-gynecologist conducting basic and applied research in the field of bioengineering. She has a specific interest in imaging techniques as they relate to the development of vaginal microbicides.

Thomas Moench is an expert in the development and testing of products to protect the reproductive health of men and women.

Lawrence R. Stanberry is an internationally recognized authority on vaccine development and viral diseases. He has authored over 175 scientific articles and led the initiation of this clinical study.

Susan L. Rosenthal has over 20 years of experience as a pediatric psychologist and is a nationally recognized expert in the area of adolescent sexual health. She has held several grants focused on the acceptability of microbicides and served as the lead senior investigator for the qualitative portion of this clinical trial.